

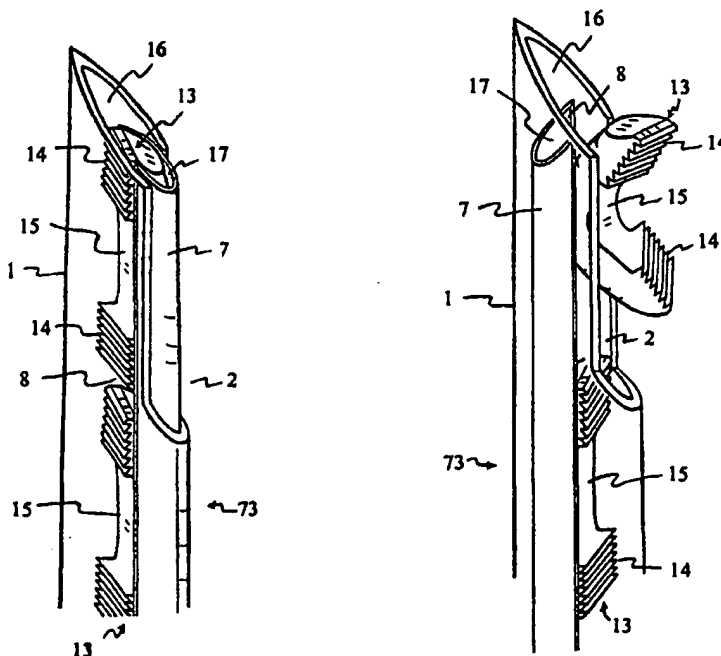


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(54) Title: TISSUE FASTENING DEVICES AND DELIVERY MEANS**(57) Abstract**

A fastener (13) and fastener delivery device (73) for guiding, delivering and deploying the fastener (13) into tissue to provide sustained gripping forces and methods of use. The fastener (13) is curved with a spring-like or shape memory material (15) and gripping elements (14). The fastener (13) is resiliently straightened and loaded into a cartridge (7) within a needle (1). The needle (1) and cartridge (7) both contain a slit (2, 8), and the slits (2, 8) extend to the distal openings (16, 17) of the needle (1) and cartridge (7). When the slits (2, 8) are not aligned, out-of-phase with each other, the fastener (13) remains resiliently straightened in the needle (1). When the slits (2, 8) overlap, in-phase with each other, the fastener (13) resiliently curves and deploys from the slits (2, 8), elastically gripping adjacent tissue. The device (73) is free to be withdrawn, allowing the fastener (13) to slide out from the distal openings (16, 17) of both cartridge (7) and needle (1).



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TISSUE FASTENING DEVICES AND DELIVERY MEANS

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FIELD OF THE INVENTION

This invention relates to sustained-holding-strength fasteners and devices and methods for delivering the fasteners into tissues.

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BACKGROUND, TRADITIONAL SURGICAL PRACTICES AND
PRIOR INVENTIONS

In recent years, much attention has been given to controlling surgical costs. One of the cost-effective approaches is to accelerate the speed of recovery and shorten post-surgical hospital stays. In addition to lowering costs, for the comfort and safety of patients, minimally invasive or endoscopic surgeries are becoming more and more popular. The term "endoscopic" used in this invention encompasses arthroscopic, laparoscopic, hysteroscopic and other instrument viewing procedures. Endoscopy is a surgical procedure, which allows surgeons to manipulate instruments to view and operate the surgical sites through small incisions in the bodies of patients.

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(A) Meniscal tear

In order to minimize both the patients' trauma and potential damage to nerves, blood vessels and other tissues, it is clearly desirable to minimize the size and number of holes puncturing the patients. Take meniscal repair in the knee for example, the current arthroscopic procedure requires one hole for the arthroscope, one hole for a needle to deliver a suture and another hole for a suture-retrieving instrument to complete one suture stitch (Arthroscopic Surgery by L. Johnson, M.D.; Knee Surgery by F. Fu, MD, et al.; Traumatic Disorders of the Knee by J. Siliski, MD; and Knee Surgery Current Practice by P. Aichroth, FRCS et al.). A minimum of three holes is made for the arthroscopic repair. In some cases, surgeons also require a distractor, an external fixation device that is screwed in through skin to the bones, separating the femur from the tibia. This expands the knee joint and makes room to manipulate both the suture and the suture-retrieving instrument. Due to the tightness of joint space, often a needle or instrument can accidentally scrape and damage the smooth surface of the joint cartilage, which given time, can potentially lead to osteoarthritis years after the surgery.

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Recently, instead of delivering, manipulating and retrieving a suture, often in a very tight surgical site, delivery of tacks with barbs (US Patent No. 5,702,462 to Oberlander, 1997; US Patent No. 5,398,861 to Green, 1995; US Patent No. 5,059,206 to Winters, 1991; US Patent No. 4,895,148 to Bays et. al., 1990; US Patent No. 4,884,572 to Bays et. al., 1989),

staples (US Patent No. 5,643,319 to Green et. al., 1997) and fasteners (US Patent No. 5,843,084 to Hart et. al., 1998; US Patent No. 5,374,268 to Sander, 1994; US Patent No. 5,154,189 to Oberlander et. al., 1992) through a small opening to hold torn tissue, such as the meniscus, in place have been implemented. Unfortunately, very few, if any, of these tacks, staples and fasteners have the holding strength to meet the standard set by sutures.

During the insertion of these devices into tissues, the barbs carve their way into their final holding position. Unavoidably, the carving damages the tissue, and thus weakens it thereby decreasing the holding strength of the freshly inserted devices. As tension is applied to the fastened tissue, it is not surprising that the barbs can lose their grip, slip and creep along the carved paths created during insertion, leaving gaps in the supposed closure sites. The creeping problem of fastening devices is particularly evident in slow healing tissues, such as menisci, and also in tissues providing high tensile strength, such as ligaments and tendons. Since gaps are present, the torn tissue does not reattach and heal, even with the passage of time.

Non-biodegradable fasteners often have the problem of device migration, which can be devastating, especially into nerves, joints or vessels, after numerous cycles of tissue remodeling.

In summary, currently most of the tacks or fasteners have one or more of the following drawbacks: (1) weak holding strength, (2) creeping and leaving gaps in the repair site, and (3) potential migration into sensitive tissues.

Numerous staples (US Patent No. 5,829,662 to Allen et. al., 1998; US Patent No. 5,826,777 to Green et. al., 1998; US Patent No. 5,817,109 to McGarry et. al., 1998; US Patent No. 5,794,834 to Hamblin et. al., 1998; US Patent No. 5,715,987 to Kelley et. al., 1998; US Patent No. 5,662,662 to Bishop et. al., 1997; US Patent No. 5,413,584 to Schulze, 1995; US Patent No. 5,333,772 to Rothfuss et. al., 1994; US Patent No. 5,304,204 to Bregen, 1994; US Patent No. 5,257,713 to Green et. al., 1993; US Patent No. 5,089,009 to Green, 1992; US Patent No. 5,002,563 to Pyka et. al., 1991; US Patent No. 4,944,295 to Gwathmey, 1990; US Patent No. 4,671,279 to Hill, 1987; US Patent No. 4,485,816 to Krumme, 1984; US Patent No. 4,396,139 to Hall et. al., 1983) are designed and used for shallow penetration of the staple, mostly to fasten superficial tissues only.

The term "fastener" used in this invention encompasses tacks, staples, screws, clamps and other tissue holding devices.

(B) Anterior cruciate ligament tear

Meniscal damage often accompanies a torn anterior cruciate ligament, ACL, which stabilizes the femoro-tibial joint. Due to the linear orientation of the collagen fibers and the enormous tensile strength required of the ACL, it is often difficult to reattach the ligament by suture. When tensile forces are applied, the suture cuts and tears the collagen fibers along their linear orientation. Therefore, the traditional ACL repair is to abandon the torn ACL altogether. To replace the ACL, a strip of patellar ligament is harvested from the patient. Two bone holes are drilled, one through the tibia and another through the femur. The strip of patellar ligament

is threaded through the bone holes. Both ends of the patellar ligaments are then stapled to the anterior surfaces of femur and tibia through incisions of skin covering each bone. The traditional ACL repair is an invasive surgery. To minimize the degree of invasiveness and eliminate opening the skin for ligament stapling, bone fixation devices (US Patent No. 5,147,362 to Goble, 1992, US Patent No. 5,129,902 to Goble, et. al. 1992) are designed to grip the ligament replacement inside the drilled hole of the bone.

(C) Bulging or herniated disc

Low-back pain is one of the most prevalent and debilitating ailments of mankind. For many people, no position can ease the pain or numbness, not even bed rest. It is often the reason for decreased productivity due to loss of work hours, addiction to pain-killing drugs, emotional distress, prolonged hospital stays, loss of independent living, unplanned early retirements, and even financial ruin. Some may experience it occasionally; others suffer from it for years. One common reason for this chronic pain is the bulging or herniation of an intervertebral disc, which can cause sciatica.

The traditional surgical treatment for a bulging or herniated disc is a series of tissue removing, filling and supporting procedures: (1) laminectomy, removal of the lamina from the vertebra which covers part of the herniated disc, (2) discectomy, removal of the disc, (3) bone harvesting usually from the patient's iliac crest, (4) bone cement filling of the donor site, (5) donor bone packing into the vacant disc space, (6) adjacent vertebra supporting with rods, connectors, wire and screws, and finally, (7) surgical site closing.

After a discectomy, numerous postoperative complications can occur. The major ones are lumbar scarring and vertebral instability. The scar tissue extends and encroaches upon the laminectomy site and intervertebral foramen, then once again, pain returns, which leads to more surgery. In fact, re-operation is very common. Unfortunately, the success rate of re-operation is often less, in some cases, far less than the first. More operations lead to more scarring and more pain. Current emphasis to the patients is to avoid surgical procedures, unless the pain and inconveniences are absolutely unbearable.

Even for the fortunate patients with long term success following discectomies twenty years ago, their isokinetic test results clearly indicate weaknesses compared to populations without discectomies.

There was and still is increasing interest in less invasive surgical techniques on the spine to reduce both trauma and cost. The major objectives of surgery on bulging or herniated lumbar discs are (1) decompression of the involved nerve root or roots, and (2) preservation of bony spine, joints and ligaments.

Chymopapain is an enzyme used to digest away the nucleus pulposus, the gel-like substance in the central portion of the disc, which then creates space for the bulging part of the disc to pull back from the encroached nerve root. The needle for injecting the chymopapain is accurately guided to the mid-portion of the disc by a stereotaxic device. The overall success rate is documented as high as 76%. However, some patients are allergic to the treatment and

die from anaphylaxis. Some others suffer from serious neuralgic complications, including paraplegia, paresis, cerebral hemorrhage and transverse myelitis (Lumbar Spine Surgery, Arthur White, M.D., Richard Rothman, M.D., Charles Ray, M.D.)

5 Percutaneous nucleotomy is an alternative method for removing nucleus pulposus without the allergic reaction of chymopapain. Similar to chymopapain injection, a needle followed by a tube-like instrument is guided and confirmed by anteroposterior and lateral fluoroscopy. The nucleus pulposus is then removed by mechanical means or by vacuum. As a result, a void is created within the disc and the bulging decreases, like the air being released from a worn out tire, with the hope that the bulging portion of the disc will recede and no
10 longer encroach upon the adjacent nerve root. This type of procedure is often referred to as a decompression procedure. Unfortunately, there is no guarantee that the decompression will reduce enough bulging or herniation to alleviate pain.

Regarding immediate postoperative complications, percutaneous nucleotomy appears to be safer than either discectomy or chymopapain. There is little epidural scarring, allergic
15 reactions, or serious neurologic complications. However, the case history using this percutaneous procedure has been relatively short, and the long-term outcome is not yet known.

The function of the nucleus pulposus, with its high water absorbing composition of mucoprotein and mucopolysaccharides, is to sustain prolonged compression during the day, and to resiliently re-inflate and re-establish disc height during the night. The pulposus is
20 retained and surrounded by layers of cartilaginous annulus. Together the pulposus and the annulus behave as a resilient and cushioning water balloon. In the erect position, the weight of the body constantly compresses upon a stack of these water balloons alternating between a series of vertebrae. During constant compression, the pulposus in each disc also behaves as a water reservoir, which is slowly and constantly being squeezed and drained of its water content
25 through the end plates connected to the vertebrae. As a result, the disc height decreases throughout the day. During bed rest, the weight of the body no longer compresses the disc. Due to the water absorbing nature of the nucleus pulposus, the flow of water is now reversed from the vascular vertebrae back into the mucoprotein and polysaccharides. As a result, the disc height is re-established, ready to provide support for another day (Clinical Biomechanics
30 of the Spine, 2nd ed., Augustus White, M.D., Manohar Panjabi, Ph.D.).

Aging, poor posture and trauma from heavy lifting contribute to an increase in annular fibrotic elements. The disc dries out and greatly loses height between vertebrae. Bone around the dried out disc grows a rim and spurs, which protrude and invade the intervertebral
35 foramina and infringe upon nearby nerves. This continual, painful bone growth process causes stenosis.

After the removal of the water absorbing and water retaining pulposus by the percutaneous procedure, the remaining disc is no longer assembled as a water balloon; the annulus becomes more like a flat tire with minimal resiliency. In the erect position, compression forces are solely exerted upon the cartilaginous annulus alone. During bed rest,

little if any water is re-absorbed by the annulus. With the passage of time, it is conceivable that the annulus will flatten out and the disc height will permanently decrease. As the vertebrae above and below the disc come closer together with less and less disc space, the growth of bone spurs and rim appear. The stenotic process has just begun. The pain returns.

5 Unfortunately, unlike the previous irritation by the bulging disc, this time the sensation of pain comes from nerve compression by solid bones. Surgical procedures can be very involved, and the potential complications and scarring can be enormous.

In short, percutaneous nucleotomy may be a quick fix for decompressing a bulging or herniated disc without allergic reaction. However, within a not so distant future, there may be a
10 much more complicated and painful ailment waiting.

Recently, several devices (US Patent No. 5,800,550 to Sertich, 1998; US Patent No. 5,683,394 to Rinner, 1997; US Patent No. 5,423,817 to Lin, 1995; US Patent No. 5,026,373 to Ray et. al., 1991) were designed to fortify the disc space between vertebrae. These types of devices are frequently referred to as spinal cages. Before inserting the device into the disc, the
15 affected disc with portions of vertebral bone above and below the disc are cored out. Usually two holes are cored, one on each side of the disc, to insert two spinal cages. Donor bone or bone-growth promoting substances are packed into the porous cages. As the vertebrae heal from the coring, new bone grows into and permanently secures the porous cages. The purpose of using spinal cages is to replace the disc and keep the vertebrae apart. However, these
20 vertebrae are permanently fused to each other, without resilient cushion, rotation or flexibility.

An improved version of a metallic spinal fusion implant (US patent 5,782,832 to Larsen and Shikhman, 1998) tries to provide both rotational and cushioning capability. This invention resembles a disc prosthesis following a complete discectomy. Therefore, at least all the complications and postsurgical problems associated with a discectomy apply when this
25 device is used.

(D) Tendon or ligament tear

In many accidents or sports related injuries, tendons or ligaments rupture from bones. Some very strong bone anchors (US patent 5,851,219 to Goble et. al., 1998; and US patent 5,478,353 to Yoon, 1995) have been invented and used with sutures to reattach ruptured
30 tissues. Attached to a suture, the anchor is inserted into a pre-drilled bone hole. The suture usually comes with a needle for sewing and attaching the torn tissue back to bone. The manipulation of suture and attachment of tissue requires not only skill and time from the surgeon, it also requires operative space in the body of the patient. To obtain the space for suture manipulation, a sizable incision or multiple incisions are often required to complete a
35 repair.

(E) Urinary or fecal incontinence

Urinary or fecal incontinence is far more common than expected. A recent finding from a large telephone survey of over 2500 households with nearly 7000 individuals reveals that for anal incontinence alone, 2.2% of the general population has the problem. Incontinent

problems, urinary and fecal alike, can and usually do alter the lifestyles of the suffering individuals, resulting in (1) social withdrawal, (2) decreased exercise, (3) altered clothing choices, (4) minimized travel, (5) avoidance of sexual relationships and/or (6) spending over \$2,000 per year for disposable or washable pads, laundry, medications and skin care products (Urology Times, February 1996).

One of the major causes of fecal incontinence in women is vaginal delivery of babies. In the United States, between 4% and 6% of women who have vaginal deliveries suffer from fecal incontinence. Fecal incontinence often coexists with urinary incontinence and may signify pudenda nerve damage. Many of these patients were found to have a weak anal sphincter, as evidenced by low anal squeeze pressures. Disruption of the anal sphincters has been attributed to episiotomies, perineal lacerations and forceps extractions.

There are several other common causes of fecal incontinence. With age, the internal anal sphincter thickens with fibrotic tissue and loses the viscoelastic properties, which are required for closure. Also, trauma can tear and permanently scar the sphincter, resulting in a continual leakage problem.

Open surgery is often performed to tighten the sphincter muscle with a suture or to replace the sphincter with an artificial elastic band. Like all other open surgeries, the incision is large; recovery is lengthy; and the medical cost is high. Furthermore, unlike most other surgical sites, which can recover undisturbed, fecal excretion is unavoidable. Sphincter repairs often encounter infection, hemorrhage, hematoma and/or other complications.

For stress urinary incontinence, there are more successful surgical procedures and effective devices to treat women than the ones used to treat men. For example, collagen, a paste-like formulation, is used to inject and bulk up the sphincter wall. Alleviating incontinence after one collagen treatment is rare for women, and it often requires five to six treatments to achieve a satisfactory level for men. Even for the individuals who endure the injections, collagen often tends to lose its bulk within a few months. Similarly, fat injections have been tried and are reabsorbed by the patient within months. Teflon-based non-absorbable materials were used, but the materials migrate away and lose their bulk and effectiveness (Urology Times, December 1997).

A disposable, inflatable urethral occlusive device has been designed for women (Urology Times, March 1995), and a penile clip for men (US patent 4,942,886 to Timmons, 1990). These devices are very unnatural and uncomfortable.

For women, there are several common and effective surgical procedures for repairing intrinsic sphincter deficiencies. A vaginal sling provides an elastic support to the sphincter unit by compressing the vaginal wall (Urology Times, July 1994). However, this surgical procedure can alter the patient's sexual function. Bladder neck closure is infrequently performed and is irreversible. Potential complications of these surgical procedures include prolonged urinary retention, suprapubic pain, cellulitis, entrapment of genitofemoral or

ilioinguinal nerve, vaginitis and/or suture infection (Glenn's Urologic Surgery, fifth edition, editor Sam Graham Jr., M.D., 1998).

(F) Carpal tunnel syndrome

5 Carpal tunnel syndrome is a painful and debilitating ailment of the hand and wrist widely believed to be caused by prolonged repetitive hand activities. Predisposing factors include congenital narrowing of the carpal tunnel, trauma to carpal bones, acute infection, endocrine imbalance, contraceptive medication or rheumatoid disease. The weakness, numbness, pain and clumsiness of carpal tunnel syndrome are mainly attributable to swelling or thickening of the tenosynovium and compression of the median nerve under the flexor
10 retinaculum. Prolonged compression can lead to narrowing of the nerve with intraneural fibrosis, resulting in irreversible loss of function.

The conservative treatment using splintage to restrict hand and wrist activity is helpful for about 70% of the patients. With the restricted hand and wrist, many patients can no longer perform their jobs. Corticosteroid injections are often effectively used to reduce the
15 inflammatory edema around the median nerve, but corticosteroids are not a long-term solution.

The most common surgical procedure for relieving compression of the median nerve is carpal tunnel decompression, which enlarges the carpal tunnel by severing the entire width of the flexor retinaculum. After the procedure, the hand is restricted for a month. Weakness and pain are felt for some time. Even with the surgical procedure, about 10% of the patients
20 experience no improvement or even more pain (Carpal Tunnel Syndrome, Bruce Conolly, FRCS, 1984).

Carpal tunnel decompression is often associated with one or more surgical complications. Early postoperative complications include hematoma, edema and infection. Subsequent common complications are weakness of grip, stiffness of fingers, wrist and
25 shoulder, adhesions of flexor tendons and/or pain from scar tissue entrapment of the cutaneous nerve (Hand Rehabilitation, 2nd Ed., Gaylord Clark, M.D, et. al.).

(G) Tumor and blood supply

Tumors, uncontrolled and rapidly growing tissues, demand extra nutrients by tapping adjacent arteries to feed and multiply the cancer cells. One of the most effective treatments of
30 tumors is surgical removal. Often, the tumor is too large or too close to delicate tissues, such as nerves. To reduce the size of the tumor prior to surgical removal, radiation and chemotherapy are commonly used. However, both of these supporting techniques are invasive to the patients, who may face a long battle with cancer. As a less invasive approach, drugs are currently under investigation for reducing the new arterial growth feeding the tumor. These
35 drugs are not likely to affect the existing arteries already feeding the tumor.

SUMMARY OF INVENTION

In keeping with the foregoing discussion, the present invention takes the form of a resilient fastener, which can be guided, delivered and deployed into tissue to provide a strong

holding strength with sustained gripping forces. The fastener may be deployed using a fastener delivery device according to the methods described herein or by other devices and methods.

5 The fastener can reattach torn tissue, anchor a suture, fortify tissue, fasten protruded tissue, elastically close a sphincter, partially close a canal, permanently close a vessel or beneficially alter the shape of tissue.

Following the deployment of the first fastener, additional fasteners can also be deployed through the same puncture site providing additional strength, especially if different holding directions and positions are utilized. The additional fasteners may be deployed without
10 completely withdrawing the delivery device from the puncture site.

The major components of the fastener delivery device are two tubes; one tube fits inside the bore of the other. For tissue penetration purposes, the outer tube can be sharpened at the distal opening and will be referred to as a needle. The main function of the inner tube is to hold the fasteners, and will be referred to as a cartridge. Both needle and cartridge have slits
15 on the walls opened to their distal openings. As the needle and cartridge rotate against each other, the slits can line up, overlapping each other. When the slits overlap, they are in-phase. When the slits do not overlap each other, they are out-of-phase. For the cartridge, the slit is preferred to be opened length-wise from the distal opening all the way to or near the proximal opening.

20 The third component of the fastener delivery device is the fastener itself. The width of the fastener is no wider than the slits in the cartridge and in the needle. At least a portion of the fastener is made with a spring-like, flexible, resilient, elastic, super-elastic or shape memory material, and at least a portion of the fastener consists of tissue gripping elements. The fastener is made with curvature and gripping elements. Due to the spring-like or shape memory
25 portion of the fastener, it can be elastically straightened either by mechanical constraint or temperature and is capable of resiliently curving back to or near the original shape when mechanical constraint is lifted or a transformation temperature is met. For simplicity, the resiliency of the fastener described in the text of this invention will concentrate on the mechanical constraint. However, it is understood that temperature may also be used.

30 The elastic fastener is or fasteners are loaded into the cartridge in the needle and resiliently straightened by at least the inner wall of the needle. In the out-of-phase mode, the most distal fastener near the distal opening of the cartridge is resiliently straightened only by the inner wall of the needle. The position of this fastener is called the deploy position, because the fastener is, in fact, ready for deployment. As the cartridge or needle rotates from the out-of
35 phase to the in-phase mode, where the mechanical constraint is removed from the fastener in the deploy position, the resiliently straightened fastener resumes its original curved shape, protruding from the slits and gripping the surrounding tissue. Since the slits of both cartridge and needle are open distally, the deployed fastener is free to slide away from the delivery device when the fastener device is withdrawn from the tissue.

To prevent fastener migration with time, tissue ingrowth holes or grooves can be channeled into the fastener.

By indenting a portion of the slit opening of the needle, one can selectively deploy a portion of the fastener while the remaining portion of the fastener remains within the device.

5 For example, the distal half of the slit is made slightly wider than the proximal half. When the needle and the cartridge slits are set nearly in-phase, or referred to hereinafter as semi-in-phase, the distal half of the fastener deploys into the surrounding tissue while the proximal half of the fastener remains within the device. A partially deployed fastener is called semi-deployed. The semi-deployed fastener is particularly helpful in endoscopic surgery. Using the gripping
10 element on the deployed distal half, a surgeon is now capable of pulling, tightening and manipulating the tissue to be fastened for a superior and gap-free repair before fully deploying the entire fastener.

To prevent the semi-deployed fastener from slipping out during tissue manipulation, tapered fastener holding elements may be carved into or incorporated onto the inner wall of the
15 needle. The holding elements provide anchoring for the portion of the fastener remaining in the needle. The tapering prevents jamming of the fastener during the transition between out-of-phase to in-phase.

Depending on the surgical needs, sometimes the proximal half of the fastener can provide better assistance in tissue manipulation than the distal half of the fastener. It is possible
20 to open the slit in ways to allow the deployment of either the distal or the proximal portion of the fastener in the semi-in-phase mode. One side of the slit is indented at the distal half while the other side of the slit is indented at the proximal half. Depending on the direction of cartridge rotation, relative to the needle, the semi-in-phase mode can bring out either the distal or the proximal end of the fastener, with tapered fastener holding elements supporting both
25 semi-deployments.

The outer needle may have penetration markers to indicate the depth of tissue penetration. Furthermore, the needle has one or more orientation lines. The line may run longitudinally from the slit through the length of the needle to indicate the deploy direction of the fastener; this orientation line is called the deploy line. In some surgical manipulations, the
30 deploy line is mostly hidden by tissues. Another orientation line may also be marked longitudinally directly opposite the deploy line, perhaps in a different color, pattern or shade; and is called the back line. The back line indicates where the back of the fastener will face.

The fourth component of the invention is a handle attached to the needle. The needle handle is made strong enough to puncture soft bone and to rotate the needle. For surgical
35 applications where both deploy line and back line are invisible by direct view or endoscope, the needle handle is fixed in a position relative to both lines to indicate the direction of fastener deployment.

The fifth component of the invention is a handle for the cartridge. The cartridge handle is attached to the cartridge and made sturdy enough to assist tissue puncturing, but the most

important function is to rotate the cartridge inside the needle. Similarly, the cartridge handle is also fixed in a position relative to the slit of the cartridge to assist in establishing the direction of fastener deployment.

Multiple fasteners can be loaded into the cartridge. After the first fastener is deployed, a fastener advancing device pushes another fastener into the deploy position. For example, a simple plunger connected to a mechanical lever can be used to advance fasteners one after another into the deploy position.

To prevent accidental puncturing of the surgeon or unintended tissue of a patient by the sharp needle, a moveable sleeve may be extended to cover the needle. In addition to the protective purpose, the sleeve can also serve numerous functions to assist surgeries. After the needle is inserted into tissue, the sleeve can be used to push and position the punctured tissue into proper place for an optimal reattachment. To fasten a bulging or herniated disc, the sleeve may be used to push and hold in the bulging annulus during the deployment of fasteners.

The fastener delivery device utilizes the rotating cartridge, relative to the needle, to deploy fasteners into tissue through overlapping slits. Similar fasteners can be resiliently straightened in a needle without the cartridge, but with a plunger fitted inside the needle behind the fastener. After insertion of the needle into tissue, the plunger is held stationary while the needle is slowly retracted or withdrawn from tissue, thereby deploying the fastener out of the distal opening of the needle. In tissue, the fastener resumes the original resilient curvature and tightly fastens onto the tissue. Multiple fasteners can also be loaded into the needle and deployed one at a time into different locations.

The fasteners can be made with alloy, pure metal, polymer, ceramic or composites. The fasteners can also be formed from modular parts, coated with lubricants, drugs, growth factors, antibiotics, hydrophilic compounds, hydrophobic compounds, self-sealing materials, swellable components, plasma coating or other substances. The curvature of the fasteners can be made symmetrical, asymmetrical or with multiple curvatures. The fasteners or parts of the fasteners can be made with biodegradable materials or with permanent materials. The fasteners or parts of the fasteners can be attached with or attached to a suture or other fastening devices.

SUMMARY OF METHODS AND ADDITIONAL EMBODIMENTS

In preparation for use, the fastener delivery device is set in the out-of-phase mode with a fastener in the deploy position. The tissue needing to be fastened is chosen, prepared and arranged. The device is then guided to the proper depth and orientation by the penetration markers, orientation line(s), endoscope, X-ray, ultrasound, MRI and/or other technique.

(A) Meniscal repair

Guided by an arthroscope and the penetration markers, the device punctures the meniscal body and traverses the tear. Through the indented slit of the needle, the distal half of the fastener with gripping element is deployed. The torn portion is gently pulled in and

manipulated back to the main body of the meniscus, then the fastener is fully deployed by setting the cartridge fully in-phase to close the tear. The device is now ready to be withdrawn, or another fastener may be deployed through the same puncture site in a different direction to ensure a tight closure.

5 To deploy another fastener, the cartridge is reset from the in-phase back to the out-of-phase position. Another fastener is advanced in the cartridge chamber to the deploy position. The needle handle may then be used to rotate the device, for example, by 180° for the deployment of another fastener. If two fasteners in the puncture site are sufficient to hold the tear at the location, the device is ready to be withdrawn from the meniscus. To prevent
10 accidental scraping of the delicate articular cartilage in the knee joint, the sleeve may be slid over the sharp needle before resetting the device to the out-of-phase position in preparation for deployment of an additional fastener or prior to withdrawal of the device.

For simplicity in the remaining method summary, operative procedures of the device, such as out-of-phase, in-phase, fastener advancement, sleeve sliding, device rotation, puncture
15 or withdrawal will not be mentioned in great detail, unless the operation is greatly varied from that described above.

(B) Ligament repair

To fortify the longitudinally oriented collagen fibers in a torn anterior cruciate ligament, ACL, some specially designed fasteners are deployed to grip and bundle the collagen fibers of
20 the ACL together like a collar. Frequently, the ACL is stretched and irreversibly lengthened prior to breaking. Therefore, the collar may not always be placed near the end of the tear. The placement of the collar is determined after manipulating and fitting the torn ACL in the patient's leg to ensure appropriate length after reattachment.

A ligament holding device may also be included to hold the ACL stationary and to
25 guide insertion of the fastener delivery device containing the collar fasteners.

For ACL tears close to the tibia or femur, a trocar is passed through the collar to the bone to establish an ACL reattachment position. A cannula is inserted as a sleeve over the trocar and contacts the bone. The trocar is then removed and replaced with a drill having drill
30 stops to prevent excessive penetration into the bone. After drilling, the drill is removed and replaced with the fastener delivery device into the drilled hole through the cannula. Unlike the collar fasteners mentioned earlier, the gripping elements for the bone attachment are designed to resist vertical or longitudinal pull out. The length of the fasteners is sufficient to span the depth of the drilled hole to beyond the collar in the torn ACL. Prior to deployment of the fasteners, the cannula is lifted beyond the slit of the needle. The collagen fibers of the ACL are
35 in contact with the delivery device, especially with the slit portion of the needle. The first fastener is then deployed. The gripping elements on one end of the fastener anchor onto the collar-fortified ACL fibers or may even latch onto the collar itself. The gripping elements on the other end of the fastener anchor into the hole in the bone. Due to the spring-like property built into the fastener body, the gripping elements at both ends are constantly compressing the

tissues, in this case the ACL fibers and bone, making the fastening strength exceptionally strong. To ensure adequately strong reattachment, multiple fasteners, preferably deployed in different directions, can be loaded into the same drilled hole without lifting the fastener delivery device.

5 Often, the ACL is torn at or near its mid-section. A similar technique using the ligament holder and collar fasteners is used to install two sets of collars, one on each torn end of the ACL. The fastener delivery device is threaded through the collars. The fastener delivery device is loaded with fasteners similar to the ones used to attach the ACL to bone. With the indented slit on the needle, partial deployment of the first fastener is helpful to pull and
10 manipulate the distal ACL fragment into place. Sliding the sleeve over the needle can also be used to push tissue, in this case the proximal ACL fragment, to tightly rejoin the distal ACL fragment. The fastener is then fully deployed, gripping both fragments of ACL fibers fortified by two sets of collars.

(C) Tendon repair

15 The fastener delivery device of the present invention can be used through a small opening to reattach a tendon back to the bone without sewing, manipulating or tying sutures. Similar to reattaching the ACL to bone, a trocar is used to pierce and guide the tendon into the proper position, where a hole will be drilled in the bone. A cannula is inserted over the trocar, and then the trocar is replaced with a drill creating a hole in the bone. The drill is then replaced
20 by the fastener device inserted through the tendon into the bottom of the bone hole. The cannula is lifted so that the slit opening of the device is in contact with tendon tissue. If necessary, the tendon can be pushed and positioned by the sliding sleeve. The fasteners in the device should have sufficient length to grip both the bone and the tendon tissue. With time, similar to the reattached ligament, the tendon can and most likely will permanently reattach
25 back onto the bone.

For soft bone, such as the humeral head in the shoulder, the needle of the device could possibly pierce a tendon to be reattached and puncture into the humerus without using the trocar, cannula and drill. The sleeve of the device may be used to manipulate the tendon for a tight and permanent repair.

30 (D) Bulging or herniated disc fastening and repair

To fasten bulging or herniated discs, the spring-like fasteners mentioned in the invention are made extra long with multiple gripping elements. For the best result, the needle of the fastener delivery device punctures the bulging portion and is guided into the disc by anteroposterior and lateral fluoroscopy or other technique. In cases where the bulging portion
35 of the disc is well concealed by the lamina of the vertebra, a small amount of the bone can be removed to allow penetration of the delivery device. When the appropriate depth is reached, the sliding sleeve is used to push and hold the bulging portion of the disc inward; the fastener is deployed to grip and compress the previously bulging tissue back in place. To make possible the push and hold technique using the sleeve during deployment of the fastener, the

distal opening of the sleeve also contains a slit, which may be oriented to overlap the slit of the needle. As the device is set in the in-phase position, the slits of the cartridge, needle and sleeve are aligned, allowing the fastener to deploy and hold the compressed tissue in place. Similar to previously mentioned surgical procedures, more than one fastener can be deployed through the puncture site, preferably toward different directions, to enhance a permanent fastening. The spring-like fasteners with multiple gripping elements provide an exceptionally strong holding strength with constant fastening forces holding back the repaired annulus, away from nerves.

The fastener directly, actively and elastically holds the bulging or herniated tissue back without removing the nucleus pulposus. Therefore the bulging or herniated disc may be repaired without loss of nucleus pulposus.

Some surgeons may like to approach the disc repair anteriorly. After retracting the abdominal contents, the device can be guided, perhaps by fluoroscope or other means, through the disc to the bulging or herniated portion. As the tip of the device reaches or nears the bulging surface, the distal half of the fastener is deployed. The bulging portion of the disc is gripped and pulled inward, then the fastener is totally deployed to fasten the bulged disc.

To prevent possible leakage of the nucleus pulposus around the fastener, prior to device insertion into the disc, a sealing patch, made with elastic and biocompatible material with closure capability, is inserted on the needle against the distal opening of the sleeve. For best results, the sleeve is fixed proximally and stationary to provide a position where the proximal tip of the soon to be deployed fastener will grip the sealing patch. Using similar guiding, inserting and compressing techniques, the sealing patch is tightly compressed, adhered or maybe even embedded into the previously bulging or herniated annulus. As the fastener is deployed, it grips the patch to seal possible leakage of nucleus pulposus. The sealing patch is a preventive measure and is optional.

Other fastening devices can be used to fasten the bulging or herniated annulus. A simple screw with tissue holding threads can be inserted through a pre-punctured hole, to compress and hold the bulging or herniated disc away from the encroached nerve. The screw can be made with a locking device to prevent loosening and/or with threads having a variable pitch to compress bulging or herniated tissue. Depending on the severity of the bulge or herniation, a simple staple or tack with tissue holding elements may be sufficient to fasten the weak annulus.

Suturing can also be used to fasten bulging or herniated discs. For example, the midsection of a small dumbbell-shaped rod is tied to a suture. The rod with suture is fitted inside a needle. Behind the rod, a plunger is inserted into the needle. The needle is guided through the bulging or herniated disc. With the plunger, the rod is pushed out of the distal opening of the needle, outside the annulus. The rod is now caught by the outer surface of the annulus and acts as an anchoring device for the suture. The needle is removed. A washer is threaded with the suture, slipped down to the bulging disc, compressed and tied. For surgical convenience, the washer can be made in conjunction with a suture-locking device to eliminate

suture tying. The suture may be made of natural or synthetic fibers, such as gut, polymers and metals.

For fastening bulging or herniated discs, other fastening devices, such as tacks, tissue anchors, staples or clamps, can also be used. To prevent possible leakage of nucleus pulposus, a sealing patch can be used in conjunction with any of the fastening devices mentioned.

(E) Urinary or fecal incontinence repair

For urinary and fecal incontinence, the spring-like fasteners of the present invention can be guided into the body and deployed to grip and elastically close the leakage of the sphincters. For insertion of the fastener delivery device, numerous existing guiding techniques, such as cystoscope, ultrasound, anteroposterior-lateral fluoroscopy, MRI or others, can be used effectively and accurately to guide the insertion and deployment of the fasteners. Again, multiple fasteners can be used to ensure proper closure of the sphincter.

To provide instant feedback to the surgeon, a pressure sensing catheter balloon, strain gauge, or tightening detecting instrument can be inserted into the leaking portion of the rectum and/or urethra. As the fastener deploys and tightens the leaking portion, the instrument can provide instant information to the surgeon regarding the placement and effectiveness of the deployed fastener. For fluoroscopic image enhancement, the catheter or instrument can be made or coated with radiopaque material to perfect the accuracy of the fastener delivery device insertion. For ultrasound image enhancement, echogenic enhancing material can be used.

Especially among elderly patients, the elasticity of sphincters varies greatly. Elasticity sensing balloons or instruments are particularly helpful in determining the elasticity of the sphincter tissues so that surgeon can select fasteners with appropriate closure strength and curvatures for optimum repairs.

(F) Carpal tunnel syndrome relief

Utilizing the elastic curvature of the fastener and the pliable nature of the flexor retinaculum, the fastener delivery device is inserted into the flexor retinaculum, perpendicular to and over the median nerve. As the fastener is deployed toward the palm inside the retinaculum, the curvature of the fastener forms the shape of an arch, lifting the flexor tissue, which was compressing the median nerve. With several other fasteners deployed side by side, a tunnel is created to relieve median nerve compression without cutting the flexor retinaculum. The fasteners can even be made with biodegradable materials, which degrade with time after relieving the pain.

(G) Double indented needle slit for versatile tissue manipulation and inter-locking fasteners

Adding to the versatility of the fastener delivery device, the slit can be double indented for semi-deploying either the proximal or distal portion of the fastener, depending on the direction of cartridge rotation. This feature is particularly helpful when alternating between fasteners to create interlocking tissue fastening. To enhance the double indented feature of the needle slit, the curvature of the fasteners can be made asymmetrical. For example, the first fastener in the deploy position is made with a curvature near the proximal end of the fastener.

The following fastener in the cartridge is made with a curvature near the distal end of the fastener. After semi-deploying the proximal half of the first fastener, the tissue is tightened by pushing, then fully deploying the first fastener. The device is slightly withdrawn and reset to out-of-phase. The following fastener is advanced into the deploy position. The distal portion of the second fastener is semi-deployed into the tissue. For the second fastener, the tissue is tightened by pulling the device before full deployment. With tissue tightening by pushing and pulling, the fasteners interlock the tissue, through one needle puncture. In addition to pushing and pulling on the semi-deployed fasteners, twisting provides yet another dimension and benefit to the tissue manipulation and inter-locking fastening.

10 (H) Tumor artery closure

With an angiogram, the location of arteries supplying a tumor is mapped out. The fastener delivery device is inserted and guided to a tumor-feeding artery. With the needle slit facing the artery, the proximal portion of the fastener is deployed under the artery. The device may then be gently pushed to compress and restrict the artery. While pushing, the fastener is fully deployed to clamp and restrict the artery. If necessary, the device is slightly withdrawn, reset and another fastener is advanced from the cartridge. The second fastener is semi-distally deployed over the artery. The device may then be gently pulled to hook and further restrict the artery. While pulling, the second fastener is fully deployed to shut the blood flow. More fasteners can be deployed to ensure a complete closure of the artery feeding the tumor.

20 (I) Other features, purposes and summary

The needle of the device may be curved with a flexible cartridge to accommodate rotation within the curved needle to reach under skin or around organs and tissue into a target site.

Many other surgical procedures can utilize the fastener and the delivery device. Some examples follow. The fastener and delivery device can endoscopically attach dislocated organs. For weight loss purposes, fasteners can be used to slow stomach emptying by restricting the pyloric sphincter or pyloric canal. The fasteners can also be used to attach medical devices inside the body.

The fastener and the delivery device can serve in numerous endoscopic procedures, which require connecting, reattaching, holding, fortifying, restricting, closing, compressing or decompressing tissues or other devices.

In brief summary, some of the possible benefits of the sustained gripping fasteners and the delivery device follow: (1) grip tissue continuously, (2) minimize fastener migration, (3) minimally invasive, (4) deploy multiple fasteners within a puncture site, (5) access deep body targets, (6) support and fortify fragile tissue, (7) reattach tissue without suture, (8) attach tissue to bone, (9) require minimal surgical space, (10) attach to other fastening devices, (11) versatile, (12) provide permanent and/or degradable fastening, (13) simple to use, (14) manipulate tissue, (15) restrict or close orifices or vessels, (16) compress or decompress tissue, and (17) provide directional fastening.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 depicts a fastener with an elastic or spring-like curvature.

Figure 2 depicts a similar fastener as the one in Figure 1 being resiliently straightened by mechanical constraint (not shown) or by temperature.

5 Figure 3 depicts an internal view of the fastener delivery device, where fasteners are resiliently straightened in the cartridge inside the needle. The needle slit and the cartridge slit are in the out-of-phase position.

10 Figure 4 depicts an internal view of the fastener delivery device in the in-phase position, where both the needle slit and cartridge slit overlap or are aligned, allowing the deployment of the distal fastener.

Figure 5 depicts an external view of the fastener delivery device in the out-of-phase position.

Figure 6 depicts an external view of Figure 5 in the in-phase position deploying a fastener.

15 Figure 7 depicts the fastener delivery device inserted into torn tissue.

Figure 8 depicts the deployment of the fastener into the tissue by setting the device from the out-of-phase to the in-phase position.

Figure 9 depicts the tissue after the device has been withdrawn, the deployed fastener continues to elastically grip the torn tissue and closes the tissue gap.

20 Figure 10 depicts a distally semi-deployed fastener from an indented needle slit.

Figure 11 depicts an inside view of the indented needle slit with tapered fastener holding elements.

Figure 12 depicts the parts of a functional fastener delivery device.

25 Figure 13 depicts a fully assembled fastener delivery device set in the out-of-phase position. The needle punctures the torn meniscus and the needle slit is positioned within the plane of the meniscus to bridge the torn tissue.

Figure 14 shows the cartridge handle turned to the semi-in-phase position to deploy the distal portion of a fastener, as indicated in Figure 10, to grip the torn tissue.

30 Figure 15 shows the torn tissue gently pulled in to tighten the torn gap with the gripping of the distally semi-deployed fastener.

Figure 16 shows the cartridge handle turned all the way to the in-phase mode to fully deploy the fastener holding the torn tissue in place.

Figure 17 shows the device reset to the out-of-phase mode by turning the cartridge handle backward.

35 Figure 18 shows the device with a fastener-advancing handle turned to place another fastener in the cartridge into the deploy position.

Figure 19 shows the delivery device turned to vary the direction of the next fastener deployment with the needle remaining in the puncture site.

Figure 20 shows the cartridge handle turned to deploy the next fastener to further secure the torn tissue.

Figure 21 shows the device withdrawn from the puncture site and the sleeve extended to cover the sharp needle to prevent scraping of articular cartilage. The fasteners remain
5 elastically fastening the torn tissue.

Figure 22 depicts a ligament-holding device.

Figure 23 depicts a torn anterior cruciate ligament, ACL, held by the ligament holder. The fastener delivery device is inserted through the guiding track near the torn tissue of the ACL.

10 Figure 24 depicts the deployed fasteners holding the ligament fibers like a collar above the torn tissue of the ACL.

Figure 25 depicts a set of tissue manipulating and bone drilling tools: a trocar, a drill and a cannula.

15 Figure 26 depicts the piercing of the trocar and the cannula through the ACL onto the surface of the bone.

Figure 27 shows the trocar replaced with a drill while the cannula is held stationary on the bone.

Figure 28 shows the cannula held stationary while the drill is replaced with the fastener delivery device inserted into the bone hole.

20 Figure 29 shows the cannula withdrawn from the ACL to allow the ACL fibers to contact the needle, especially the needle slit.

Figure 30 depicts the anchoring of the ACL fortified by three fasteners extending from the cone-shaped hole in the bone to beyond the collar fasteners around the ACL.

25 Figure 31 shows an ACL rupture more distant from bone. Two sets of collar fasteners are installed near the torn ends of the ACL. Three fasteners are deployed to reattach the collar fasteners fortifying the ACL fragments.

Figure 32 depicts a tendon torn from the humerus. A fastener delivery device is inserted into the tendon and pierces the humerus.

30 Figure 33 shows the tendon being positioned by the sleeve, as the tendon is reattached to the humerus.

Figure 34 depicts a long fastener with spring-like or shape memory elements and multiple gripping elements.

35 Figure 35 depicts a nerve retractor lifting an impinged nerve away from a bulging or herniated disc. A fastener delivery device is inserted with a sealing patch into the bulging or herniated portion of the disc.

Figure 36 depicts the compression of the bulging disc by the sleeve. The sealing patch is also pressed against the bulging disc.

Figure 37 shows the cartridge handle turned to deploy the fastener into the disc while the sleeve and sealing patch compress the bulge.

Figure 38 shows the device withdrawal with the fastener remaining within the disc, gripping and fastening the previously bulging annulus.

Figure 39 depicts a sealing patch gripped by the proximal portion of the fastener outside the repaired annulus (not shown).

5 Figure 40 depicts a disc fastening screw with a washer used to fasten a bulging or herniated disc.

Figure 41 depicts the fastening of the previously bulging or herniated disc by the disc fastening screw.

10 Figure 42 depicts another bulging or herniated disc fastening device using a suture tied to a dumbbell shaped rod. A plunger is used to deploy the rod and a washer is used for tying with the suture to compress the bulging disc.

Figure 43 depicts the assembly of the rod, suture and plunger inside a spinal needle.

Figure 44 depicts a puncture using the spinal needle containing the assembly of the rod, suture and plunger, as indicated in Figure 43, through the bulging or herniated disc.

15 Figure 45 shows the rod tied to the suture and deployed out of the distal opening of the spinal needle and out of the disc by the pushing of the plunger.

Figure 46 shows the spinal needle withdrawn. The rod is anchored outside the disc holding the suture. The washer is then threaded through with the ends of the suture.

20 Figure 47 shows the previously bulging disc compressed by the washer and fastened by a suture knot.

Figure 48 depicts a staple with annulus-holding barbs configured to compress and fasten a bulging disc.

Figure 49 depicts another type of staple with closure or shape memory legs to hold and fasten a bulging disc.

25 Figure 50 depicts an insertion of the fastener delivery device to deploy an elastic fastener into a leaking anal sphincter.

Figure 51 depicts a deployed fastener, indicated by the dotted curvature, around the anal sphincter. The device is reinserted into another portion of the sphincter to deliver another fastener.

30 Figure 52 depicts an elastic closure of the anal sphincter, in this case with two spring-like fasteners.

Figure 53A depicts a leaking sphincter due to incomplete closure.

Figure 53B depicts the partial closure of the sphincter by a spring-like fastener.

Figure 53C depicts the elastic closure of the sphincter by two spring-like fasteners.

35 Figure 54 depicts possible entries for the fastener delivery devices for treating urinary and fecal incontinence. Tightening detecting instruments provide instant feedback to the surgeon after each fastener is deployed.

Figure 55 depicts a hand with carpal tunnel syndrome and insertion of a fastener delivery device into the flexor retinaculum (not shown) under the skin.

Figure 56 depicts several deployed fasteners lifting the flexor retinaculum, creating a tunnel to accommodate the irritated median nerve (not shown) beneath it.

Figures 57A & B depict two fasteners with asymmetrical curvatures to enhance the effectiveness of inter-locking fasteners.

5 Figure 58 depicts a needle of the fastener delivery device with a double indented slit to allow semi-deployment of either the distal or proximal portion of a fastener (not shown). Tapered fastener holding elements are indicated to anchor either semi-deployment.

Figure 59 depicts a proximally semi-deployed fastener pushing, compressing and restricting an artery feeding a tumor.

10 Figure 60 shows the fastener of Figure 59 fully deployed. Another fastener is distally semi-deployed, pulling and further restricting the blood flow of the artery.

Figure 61 depicts both fully deployed, inter-locking fasteners restricting blood flow to the tumor.

Figure 62 depicts a fastener with tissue ingrowth holes to minimize fastener migration.

15 Figure 63 depicts another fastener with tissue ingrowth grooves designed to minimize fastener migration.

Figure 64 depicts a fastener attached to a suture.

Figure 65 depicts a simple fastener delivery device. A curved fastener is resiliently and elastically straightened in a needle followed by a plunger for deployment.

20 Figure 66 depicts modular gripping elements with stems fitting into the gripping element holes.

Figure 67 depicts the assembled fastener with two modular gripping elements.

Figure 68 depicts the sloped indentation of the needle slit with a deploy line indicating the direction of fastener deployment.

25 Figure 69 depicts the slanted indentation of the needle slit for selecting initial protrusion of fastener deployment.

Figure 70 depicts modular arms with connecting studs and hooks into connecting holes in a spring-like or shape memory element.

Figure 71 depicts an assembled fastener with modular parts.

30 Figure 72 depicts the back line of the needle.

Figure 73 depicts a curved needle with cartridge and fastener in out-of-phase mode with the needle slit.

DETAILED DESCRIPTION OF THE EMBODIMENTS

35 In the present invention, a fastener can be guided, delivered and deployed into tissue to provide a strong holding strength with sustained gripping forces. The fastener can reattach torn tissue, anchor a suture, fortify a tissue, fasten protruded tissue, elastically close a sphincter, partially close a canal, permanently close a vessel or beneficially alter the shape of a tissue.

Figure 1 depicts a fastener 13 formed of an elongated body being elastically predisposed toward a curvature. When the fastener 13 assumes the curvature, it is in the closed position. The ends of the fastener 13 are blunt, rounded, flat, etc., thereby decreasing the likelihood of the fastener 13 puncturing the surrounding tissue. A plurality of gripping elements 14 are formed on one side of the fastener 13, near each end. Further gripping elements 14 may be located on other sides to decrease the likelihood of migration of the fastener 13. All or a portion of the fastener 13 contains or is made of a spring-like or shape memory element 15, thereby predisposing the fastener 13 towards the curved configuration. If the shape memory element 15 is made with temperature sensitive material such as nickel titanium, transformation temperature is also very important.

Figure 2 depicts a similar fastener 13 as the one in Figure 1 being resiliently straightened by mechanical constraint, not shown, or by temperature acting on the shape memory element 15 of the fastener 13. The fastener 13 indicated is in an extended or open position.

The fastener 13 has a preferred range of lengths between 1.0 mm and 200 mm, more preferably between 3.0 mm and 70 mm. The fastener 13 has a preferred width of 0.1 mm to 30 mm, more preferably between 0.5 mm and 7.0 mm. Although not required, the fastener 13 is preferably configured such that the resilient member does not exceed the elastic limit of the material chosen. For example, a stainless steel resilient member's strain should not exceed approximately 2%. A nickel titanium resilient member's strain should not exceed 7-14%. The maximum strain varies depending on the alloy, heat treatment and coldworking. If a polymer is used the percent of strain varies significantly depending on the particular polymer chosen.

For the gripping elements 14 of the fasteners 13, the shape, direction, depth, pitch, angle, pattern, density, size and material can vary and certainly are important for effective tissue fastening. The gripping elements 14 may be grooves, as shown, or other shapes such as chevrons, bumps, etc. Some cases require strong gripping power, while other cases require a weak grip. The characteristics of the gripping elements may be adjusted to maintain the desired grip. The structure, size, shape, length, elasticity of the material and curvature of the spring-like or shape memory element 15 are also important factors in determining the intensity of the grips of the fastener 13.

The gripping elements 14 and the spring-like or shape memory element 15 of the fastener 13 can be made with one material or with multiple materials. The materials used in making the fastener 13 can be degradable, permanent or a combination of both. Due to the strength, superelastic and shape memory properties, nickel titanium is the preferred material for making at least a portion of the fasteners 13. For biodegradable properties, polylactic resin, polyglycolic resin, biomaterial or other polymers can be used. Other metals, alloys, polymers, ceramics or composites can also be used.

The fasteners 13 can be coated or blended with lubricants, tissue compatible components, antibiotics, growth factors, tissue sealing materials, hydrophilic or hydrophobic

materials, drugs, drug releasing substances, swellable components, coatings, plasma coatings and/or others.

The fasteners 13 can also be formed in one piece or from modular parts, discussed with figures 66, 67, 70 and 71. The parts can be coated with or contain lubricants, drugs, growth factors, antibiotics, hydrophilic compounds, hydrophobic compounds, self-sealing materials, swellable components, plasma coating or other substances.

The fastener 13 or parts of the fastener 13 can be made with biodegradable materials, such as polylactic resin, polyglycolic resin or other polymer. Biomaterials, such as collagen, elastin or others, can also be used as a biodegradable component in the fastener 13.

In addition to alloys or metals, numerous long lasting polymers can be used to make the fastener 13 or part of the fasteners 13. Polypropylene, polyethylene, polytetrafluoroethylene (PTFE) and many other polymers may meet the requirements.

As will be discussed in further detail later, the curvature of the fasteners 13 can be made symmetrical, asymmetrical or with multiple curvatures. The fasteners 13 or parts of the fasteners 13 can be attached with or attached to a suture 21 or other fastening devices.

Figure 3 depicts an internal view of the fastener delivery device 73. Figure 4 depicts an internal view of the fastener delivery device 73 in the in-phase position. Figure 5 depicts an external view in the out-of-phase position. Figure 6 depicts an external view in the in-phase position.

The major components of the fastener delivery device 73 are two tubes 1, 7; one tube fits inside the bore of the other. For tissue penetration purposes, the outer tube can be sharpened at the distal opening 16 and will be referred to as a needle 1. The main function of the inner tube is to hold the fasteners 13, and will be referred to as a cartridge 7. Both needle 1 and cartridge 7 have slits 2, 8 on the walls opened to their distal openings 16, 17. As the needle 1 and cartridge 7 rotate against each other, the slits 2, 8 can line up, overlapping each other. When the slits 2, 8 overlap, they are in-phase. When the slits 2, 8 do not overlap each other, they are out-of-phase. For the cartridge 7, the slit 8 is preferred to be opened length-wise from the distal opening 17 all the way to or near the proximal opening.

The third component of the fastener delivery device 73 is the fastener 13 itself. The width of the fastener 13 is no wider than the slits 2, 8 in the needle 1 and in the cartridge 7. At least a portion of the fastener 13 is made with a spring-like, flexible, resilient, elastic, superelastic or shape memory material 15, and at least a portion of the fastener 13 consists of tissue gripping elements 14. The fastener 13 is made with curvature and gripping elements 14. Due to the spring-like or shape memory 15 portion of the fastener 13, it can be elastically straightened to the extended or open position either by mechanical constraint or temperature and is capable of resiliently returning to or near the original curved configuration or closed position when mechanical constraint is lifted or temperature is met. For simplicity, the resiliency of the fastener 13 described in the text of this invention will concentrate on the mechanical constraint. However, it is understood that temperature may also be used. The

elastic fastener 13 is or fasteners 13 are loaded into the cartridge 7 in the needle 1 and resiliently straightened by at least the inner wall of the needle 1. In the out-of-phase mode, the most distal fastener 13 near the distal opening 17 of the cartridge 7 is resiliently straightened only by the inner wall of the needle 1. The position of this fastener 13 is called the deploy position,

5 because the fastener 13 is in fact ready for deployment. As the cartridge 7 or needle 1 rotates from out-of-phase to the in-phase mode, where the mechanical constraint is removed from the fastener 13 in the deploy position, the resiliently straightened fastener 13 resumes its original curved shape, protruding from the slits 2, 8 and gripping the surrounding tissue. Since the slits 2, 8 of both needle 1 and cartridge 7 are open distally, the deployed fastener 13 is free to slide
10 away from the delivery device 73 when the fastener delivery device 73 is withdrawn from the tissue.

The outer needle 1 has penetration markers 3 to indicate the depth of tissue penetration. Furthermore, the needle 1 has one or more orientation lines, seen in figures 58 and 72. The orientation line may run longitudinally from the slit 2 through the length of the needle 1 to
15 indicate the deploy direction of the fastener 13; this longitudinal line is called the deploy line 65. In some surgical manipulations, the deploy line 65 is mostly hidden by tissues. Another longitudinal line, the back line 66, perhaps in a different color, pattern or shade is also marked longitudinally directly opposite the deploy line 65. The back line 66 indicates where the back of the fastener 13 will face.

20 Figure 3 shows the fasteners 13 resiliently straightened by mechanical restraint in the cartridge 7 inside the needle 1. The needle slit 2 and the cartridge slit 8 are in the out-of-phase mode with a fastener 13 in the deploy position and another fastener 13 below it. Under the constrained condition, both fasteners 13 are in open position.

Figure 4 depicts an internal view of the fastener delivery device 73, where both the
25 needle slit 2 and cartridge slit 8 are aligned or overlapped. Both slits 2 and 8 are open to distal openings 16, 17 of the needle 1 and cartridge 7. As the slits 2, 8 align or overlap each other, the mechanical restraint is relieved for the distal fastener 13. The fastener 13 resumes the curved shape by exhibiting a closed or clamped position and is elastically deployed from the slit 2 of the needle 1. In the clamped position, the gripping elements 14 are on the concave side
30 of the closed fastener 13. But the proximal fastener 13 remaining in the fastener delivery device 73 is still resiliently restricted beneath the slit 2 of the needle 1.

Figure 5 depicts an external view of the fastener delivery device 73 in the out-of-phase mode. The top portion of a fastener 13 in the deploy position is visible near the distal opening 17 of the cartridge 7. Penetration markers 3 are indicated on the needle 1.

35 Figure 6 depicts an external view of Figure 5 in the in-phase mode deploying a fastener 13. The fastener 13 resumes the resilient curvature and protrudes out the slit 2 of the needle 1.

In preparation for use, the fastener delivery device 73 is set in out-of-phase mode with a fastener 13 in the deploy position. The tissue needing to be fastened is chosen, prepared and arranged. The device 73 is then guided to the proper depth and orientation by the penetration

markers 3, deploy line 65, back line 66, endoscope, X-ray, ultrasound, MRI and/or other technique.

Figure 7 depicts the fastener delivery device 73 punctured 32 into a torn tissue 22. Guided by the penetration markers 3, endoscope or other viewing technique, the slit 2 of the needle 1 is positioned to bridge the tear. The direction of fastener deployment is easily controlled by simply turning the needle 1 of the device 73.

Figure 8 depicts the deployment of the fastener 13 into tissue by setting the device 73 from out-of-phase to the in-phase mode. With gripping elements 14, the torn tissue 22 is being gripped; and the resumed curvature of the fastener 13 closes the torn tissue 22 gap. When the device 73 is withdrawn, the deployed tissue gripping fastener 13 can slide out from the device 73 along both the slit 2 of needle 1 and the slit 8 of cartridge 7 shown in Figure 4 since both slits 2, 8 are open to the distal openings 16, 17 of needle 1 and of cartridge 7, also shown in Figure 4.

Figure 9 depicts the tissue after the device 73 has been withdrawn, the deployed fastener 13 continues to elastically grip torn tissue 22 and closes the tissue gap. The depicted curvature of the fastener 13 is between the resiliently straightened curvature in Figure 2 and the full curvature depicted in Figure 1 to indicate that torn tissue 22 is under sustained closure forces exerted by the fastener 13.

Following the deployment of the first fastener 13, additional fasteners 13 can also be deployed through the same puncture site 32 providing additional strength, especially if different holding directions and positions are utilized. The additional fasteners 13 may be deployed without completely withdrawing the delivery device 73 from the puncture site 32.

Figure 10 depicts an example of an indented needle slit 2, where the distal portion 74 of the needle slit 2 is wider than the proximal portion 75 of the needle slit 2. By indenting the slit 2 of the needle 1, one can selectively deploy a portion of the fastener 13 while the remaining portion of the fastener 13 remains straightened within the needle 1 of the device 73. When the needle slit 2 and the cartridge slit 8 are set nearly in-phase, or called semi-in-phase, the distal half 76 of the fastener 13 deploys into the surrounding tissue while the proximal half 77 of the fastener 13 remains within the device 73. The half-deployed fastener 13 is particularly helpful in endoscopic surgery. Using the gripping elements 14 on the deployed distal half 76, a surgeon is now capable of pulling, tightening and manipulating the tissue to be fastened for a superior and gap-free repair before fully deploying the entire fastener 13.

To prevent the half-deployed fastener 13 from slipping out during tissue manipulation, fastener holding elements 60 may be carved as grooves into or incorporated onto the inner wall of the needle 1, as shown in figure 11 which depicts the inside view of the indented needle slit 2 with the fastener holding elements 60. The holding elements 60 may be tapered from very shallow ridges to taller ridges as they near the needle slit 2. The fastener holding elements 60 in this example are designed to hold the proximal portion 77 of the semi-deployed fastener 13 during pulling and tissue manipulation by surgeons. The fastener holding elements 60 are

tapered to minimize fastener 13 jamming during rotation from out-of-phase to the semi-in-phase mode.

In an alternate embodiment, the entire fastener 13 may be deployed through the distal opening 16 of the needle 1 by removing the needle while holding a plunger within the needle 1 stationary. This embodiment may still be used to manipulate the tissue after the distal end of the fastener 13 has been deployed, but before the proximal end of the fastener 13 is deployed. The proximal portion of the fastener 13 could be deployed by removal of the needle allowing the entire fastener 13 to exit through the distal opening 16, or the proximal portion of the fastener 13 could deploy through the slit 2 of the needle 1. In this embodiment, the slit 2 could be shortened or omitted since none or only a small portion of the fastener 13 need exit the side of the needle 1.

Other embodiments may have the edge of the slit 2 in the needle angled or tapered to gradually bring the fastener 13 towards its deployed configuration prior to full deployment or the edge may have a straight edge, i.e. cut generally perpendicular to the perimeter of the needle 1.

Figure 12 depicts an example of a functional fastener delivery device 73 with individual parts. The device assembly follows. The sleeve 18 fits over the needle 1. To keep both sleeve slit 19 and needle slit 2 aligned or overlapping, a sleeve handle 20 is inserted into a sleeve-sliding track 59 to prevent the sleeve 18 from rotating. The proximal opening of the needle 1 is in the needle body 61. The cartridge 7 extending from the cartridge body 62 is inserted through the proximal opening of the needle 1. The cartridge body 62 is housed in the needle body 61. The cartridge 7 and the cartridge body 62 are operated by a cartridge handle 9, which extends through the side of needle body 61. The cartridge units are retained by a cartridge cap 58. For advancing fasteners 13, not shown, in the cartridge, a fastener-advancing plunger 10 is inserted through a hole of the cartridge cap 58 and the cartridge body 62 into the proximal opening of the cartridge 7. The fastener-advancing device 11 works in conjunction with the cartridge body 62 to advance fasteners. At the proximal end, a fastener-advancing handle 12 is used to drive the advancing units, pushing the fastener toward the deploy position. In the out-of-phase position, fasteners 13, not shown, can then be loaded, one by one, through the distal openings 16, 17 of the needle 1 and the cartridge 7.

The needle handle 6 is made strong enough to puncture soft bone and to rotate the needle 1. For surgical applications where both deploy line 65 and back line 66 are invisible by direct view or endoscope, the needle handle 6 is fixed in a position relative to both lines 65, 66 to indicate the direction of fastener 13 deployment.

The cartridge handle 9 is made sturdy enough to assist tissue puncturing, but the most important function is to rotate the cartridge 7 inside the needle 1. Similarly, the cartridge handle 9 is also fixed in a position relative to the slit 8 of the cartridge 7 to assist in establishing the direction of fastener 13 deployment.

Multiple fasteners 13 can be loaded into the cartridge 7. After the first fastener 13 is deployed, a fastener advancing device 11 pushes another fastener 13 into the deploy position. For example, a simple plunger 10 connected to a mechanical lever acting as a handle 12 can be used to advance fasteners 13 one after another into the deploy position.

5 To prevent accidental puncturing of the surgeon or unintended tissue of a patient by the sharp needle 1, a moveable sleeve 18 may be extended to cover the needle 1. In addition to the protective purpose, the sleeve 18 can also serve numerous functions to assist surgeries. After the needle 1 is inserted into tissue, the sleeve 18 can be used to push and position the punctured tissue into proper place for an optimal reattachment. To fasten a bulging or herniated disc 41,
10 the sleeve 18 can be used to push and hold in the bulging annulus during the deployment of fasteners 13. Skilled surgeons may also prefer to add rotational movements using tissue manipulating elements at the distal end of the sleeve 18.

(A) Meniscal repair

15 Within the body, there are a number of menisci, typically near circular or crescent-shaped fibrocartilage or dense fibrous tissue structures which appear between bones. For the example given herein, meniscus will refer to a meniscus within the knee, however, the technique may be used on other menisci and other similar structures.

For meniscal repair, the device 73 is effective for both outside-in and inside-out approaches. The outside-in approach is to enter from the thick peripheral rim of the meniscus
20 26 toward the thin tapering portion of the meniscus 26. The inside-out approach is to enter from the thin portion toward the thick rim. The inside-out approach is more frequently used by surgeons using suture or meniscal tacks because it is less likely to rupture vessels and nerves. The fasteners 13 and delivery device 73 in the invention can accommodate both approaches. However, the drawings and method summary are depicted using the inside-out
25 approach only.

Figure 13 depicts a very common meniscal tear 22 near nerves 25, arteries 23 and veins 24 in the knee of a patient. If the repair is done with suture, skin and muscle would be opened and the nerves 25, arteries 23 and veins 24 would all be retracted to prevent possible damage during suture passage and manipulation. For fastener 13 repair, nothing passes
30 through the delicate area; therefore, opening the skin and muscle of the patient to retract the nerve 25 and blood vessels is not necessary. A fully assembled fastener delivery device 73 is set in the out-of-phase mode. Guided by an arthroscope, not shown, and penetration markers 3, the needle 1 punctures the torn meniscus 26 and the needle slit 2 is positioned within the plane of the meniscus to bridge the torn tissue 22. Through the indented slit 2 of the needle 1,
35 the distal half 76 of the fastener 13 with gripping element(s) 14 is deployed as indicated in figure 14.

Figure 15 shows the torn tissue 22 gently pulled in to tighten the torn gap with the gripping elements 14 of the distally semi-deployed fastener 13; in this case, it also grips the capsule 27.

Figure 16 depicts the cartridge handle 9 turned all the way to the in-phase mode to fully deploy the fastener 13 holding the torn tissue 22 in place. The device is ready to be withdrawn, allowing the deployed fastener 13 to slide out of the distal openings 16, 17 of the needle 1 and the cartridge 7 indicated in Figure 4.

5 For the highest holding strength, the tear 22 should be at or near the mid-portion of the fastener 13. The direction of fastener 13 deployment is preferably within the plane of the meniscus 26. The device 73 is now ready to be withdrawn, or another fastener 13 may be deployed through the same puncture site in a different direction to ensure a tight closure.

10 To deploy another fastener 13 into the puncture site, the cartridge 7 is reset from in-phase back to out-of-phase mode as indicated in figure 17. However, it is possible that a portion of the deployed fastener 13 may remain in the cartridge 7 and restrict the cartridge 7 from rotating back to the out-of-phase mode. To free the cartridge 7 from the deployed fastener 13, the device may have to be slightly withdrawn from the puncture site 32 to depart or be free from the deployed fastener 13 prior to rotating.

15 Figure 18 shows the device 73 with the fastener-advancing handle 12 turned to position another fastener 13 in the cartridge 7 into the deploy position. The fastener-advancing device 11, not shown in this figure, is preferred to provide advancement of one fastener length for each semi-rotation of the fastener-advancing handle 12. Other mechanical designs for advancing fasteners 13 are possible.

20 The needle handle 6 may then be used to rotate the device 73, for example, by 180° as shown in figure 19. Presumably the first fastener 13 has already closed the tear 22, so tissue manipulation by the half-deployed fastener 13 technique is probably unnecessary. The second fastener 13 may, therefore, be fully deployed as shown in figure 20 to further secure the torn tissue 22. In this case, two fasteners 13 are deployed within the plane of the meniscus and with the deployment directions 180° from each other, within the puncture site.

25 Figure 21 shows the device withdrawn from the puncture site 32. The fastener 13 slides through the slits 2, 8 and distal openings 16, 17 of both needle 1 and cartridge 7, as indicated in Figure 4, and elastically fastens the torn tissue 22. In this case, there are a total of two deployed fasteners 13 holding the torn portion 22 of the meniscus 26. The sleeve 18 is then extended to cover the distal end of the needle 1 to prevent scraping of articular cartilage after the device 73 is withdrawn and possibly reset within the knee joint. Another fastener 13 can be advanced for another fastening if desired.

30 Due to the enormous pressures exerted at the femoro-tibial joint, meniscal tacks in the market today can creep and leave unhealing gaps along the meniscal tear. The spring-like fasteners 13 in this invention, on the other hand, provide not only strong holding strength, they also provide spring-like closure forces rejoining the torn tissue 22, thereby allowing the meniscus 26 to serve its function and to heal.

Although meniscal suture repair is believed to be reliable, it requires multiple and/or large incisions or entry points; and retractors are often required to pull aside blood vessels,

5 nerves and even expand joint space for passage and manipulation of the suture. Each of these retractions involves risks, post-surgical complications, prolonged healing time and increased medical costs. On the other hand, the delivery device 73 for the spring-like fasteners 13 in the present invention consists of a needle 1 and components in the needle 1, which only require a small entry for fastener 13 delivery.

For simplicity in the remaining method descriptions, operative procedures of the device 73, such as out-of-phase, in-phase, fastener 13 advancement, sleeve 18 sliding, device 73 rotation, puncture or withdrawal will not be mentioned in great detail, unless the operation is greatly varied from that described above.

10 (B) Ligament repair

During injury, meniscal 26 tears often accompany torn anterior cruciate ligaments 28 (ACL). As mentioned, the linear orientation of collagen fibers in the ACL 28 and the tensile strength requirement make it difficult to securely reattach the tear by suture, staple or any other existing means. Frequently, another ligament in the body is harvested or an artificial prosthetic device is used with extensive surgical incisions, drillings and attachments to replace the ACL 28.

15 To fortify the longitudinally oriented collagen fibers in a torn ACL 28, some specially designed fasteners 13 are deployed to grip and bundle the collagen fibers of the ACL 28 together like a collar. Frequently, the ACL 28 is stretched and irreversibly lengthened prior to breaking. Therefore the collar may not always be placed near the end of the tear. The placement of the collar is determined after manipulating and fitting the torn ACL 28 in the patient's leg to ensure appropriate length after reattachment.

Figure 22 shows a ligament holding device 81 with a handle 31, device guiding tracks 30 and a ligament holder 29. The ligament holding device is designed to hold the ACL 28 stationary and to guide insertion of the fastener delivery device 73 containing the collar fasteners 13 during endoscopic repair of a ligament 28.

20 Figure 23 shows a torn ACL 28 held by the ligament holder 29. Guided by an arthroscope, not shown, through the device guiding track 30, the fastener delivery device 73 is inserted near the torn tissue 22 of the ACL 28. Specifically designed fasteners 13 for gripping and holding ligament fibers are deployed in the ACL 28, in this example, one on each side positioned by the guiding tracks 30.

Figure 24 depicts the deployed fasteners 13 holding the ligament fibers like a collar or ring above the torn tissue 22 of the ACL 28. The curvature and closure strength of the collar fasteners 13 are designed to hold, bundle and fortify the collagen fibers of the ligament 28. 35 The gripping elements 14 of the collar fasteners 13 are designed and directed to resist, in this example, the downward pulling forces. The fastener delivery device 73 puncture sites 32 are shown.

Figure 25 depicts a set of tissue manipulating and bone drilling tools for reattaching a torn ligament or tendon. For ACL tears close to the tibia or femur, a trocar 33 having a sharp

distal tip is passed through the collar to the surface of the bone 38 to establish an ACL 28 reattachment position. A cannula 34 with a handle and a sharp distal tip is inserted over the trocar 33 and contacts the bone 38, as shown in figure 26. The trocar 33 is then removed and replaced with a drill 35, as shown in figure 27. While the cannula 34 is held stationary on the bone 38, a hole is drilled into the bone 38, with depth predetermined by the bone stop 36 and cannula stop 37, as indicated in figure 25. Figure 28 shows the cannula 34 held stationary, while the drill 35 is replaced with the fastener delivery device 73 set out-of-phase and inserted into the bone hole.

Unlike the collar fasteners 13 mentioned earlier, the gripping elements 14 for the bone 38 attachment are designed to resist vertical or longitudinal pull out. The length of the fasteners 13 is sufficient to span the depth of the drilled hole to beyond the collar of the torn ACL 28, depicted in figure 24. Prior to deployment of the fasteners 13, the cannula 34 is lifted beyond the slit 2 of the needle 1, as shown in figure 29. The collagen fibers of the ACL 28 are in contact with the delivery device 73, especially with the slit 2 portion of the needle 1. The first fastener 13 is then deployed.

Figure 30 depicts the gripping of three deployed fasteners 13 after the withdrawal of the fastener delivery device 73. The distal portion of the fasteners 13 in the cone-shaped bone hole tightly grip and anchor the bone 38. The proximal portion of the fasteners 13 grip the collar-fortified ACL 28 fibers. Due to the spring-like property built into the fastener body 13, the gripping elements 14 at both portions are constantly compressing the tissues, in this case the ACL 28 fibers and bone 38, making the fastening strength exceptionally strong. To ensure adequately strong reattachment, multiple fasteners 13, preferably deployed in different directions, can be loaded into the same drilled hole without completely lifting the fastener delivery device 73.

For deployment of multiple fasteners 13, the device 73 in the puncture site 32 is reset to the out-of-phase mode. As mentioned, it is possible that a portion of the deployed fastener 13 may remain in the cartridge 7 and restrict the cartridge 7 from rotating back to the out-of-phase mode. To free the cartridge 7 from the deployed fastener 13, the device 73 may have to be slightly withdrawn from the puncture site 32 to depart or be free from the deployed fastener 13 prior to rotation. Another fastener 13 may then be advanced to the deploy position within the cartridge 7. The device 73 is rotated slightly to alter the direction of the next fastener 13 deployment. This procedure is repeated until the torn ACL 28 is tightly fastened onto the bone 38.

Often, the ACL 28 is torn at or near its mid-section. A similar technique with the ligament holder 29 and collar fasteners 13 is used to install two sets of collars, one on each torn end of the ACL 28. The placements of these collar fasteners 13 also are determined after manipulating and fitting the ACL 28 fragments in the patient's leg to ensure appropriate length after reconnecting the ACL 28.

To attach two collar fortified ACL 28 fragments, the needle 1 is inserted through both sets of collars, bridged by the indented slit 2. Distally semi-deploying the first fastener 13 may be helpful to pull and manipulate the distal ACL 28 fragment into place. Sliding the sleeve 18 over the needle 1 can also be used to push tissue, in this case the proximal ACL 28 fragment, to tightly rejoin the ACL 28 fragments. The fastener 13 is then fully deployed, gripping both fragments of ACL 28 fibers fortified by two sets of collars 13. Due to the high tensile strength required during normal function of the ACL 28, adding multiple fasteners 13 is recommended to ensure a successful ACL 28 repair. Therefore, after the initial fastener 13 deployment, the device 73 is reset to out-of-phase mode, another fastener 13 is advanced, and the device 73 is rotated to deploy another fastener 13. The procedure is repeated until the two ACL 28 segments are firmly reattached by the deployed fasteners 13, as shown in figure 31. Again, it is possible that a portion of the deployed fastener 13 may remain in and restrict the rotation of the cartridge 7. A slight withdrawal of the device 73 may be necessary before resetting it to the out-of-phase mode.

In alternate methods, the collar fasteners 13 may be tied with sutures to another set of collar fasteners 13, to a tunnel through the bone 38, a bone anchor, etc.

By fortifying and reattaching the torn ACL 28 with fasteners 13, the patient has avoided the trauma of replacement harvesting and extensive bone drilling required by conventional ACL 28 repair.

(C) Tendon repair

A tendon 40 torn from the bone 38 is common among sport injuries and accidents. Generally, there are two major approaches for reattaching a tendon 40 back to the bone 38. The traditional repair is to drill through the bone 38, then pass a suture to attach the torn tendon 40 back to the bone 38. Recently, tendon 40 repair has been done using less invasive drilling and artificial bone anchors with attaching sutures, which are fitted into a shallowly drilled hole in the bone 38. Even with bone anchors, suture manipulation requires both time from surgeons and surgical space within the patient, which may lead to large or multiple incisions.

Similar to reattaching the ACL 28 to the bone 38, a trocar 33 is used to pierce and guide the tendon 40 into proper position, where a hole will be drilled in the bone 38. A cannula 34 is inserted over the trocar 33, and then the trocar 33 is replaced with a drill 35 creating a hole in the bone 38. The drill 35 is then replaced by the fastener delivery device 73 inserted through the tendon 40 into the bottom of the bone hole. The cannula 34 is lifted so that the slit 2 opening of the needle 1 is in contact with tendon tissue 40. If necessary, the tendon 40 can be pushed and positioned by the sliding sleeve 18. The fasteners 13 in the device 73 should have sufficient length to grip both the bone 38 and the tendon tissue 40. With time, similar to the reattached ligament, the tendon 40 can and most likely will permanently reattach back onto bone 38.

For soft bone, such as the humerus 39 in the shoulder, the needle 1 of the device 73 could possibly pierce a tendon 40 to be reattached and puncture into the humerus 39 without

using the trocar 33, cannula 34 and drill 35. Figure 32 depicts a tendon 40 torn from the humerus 39. The fastener delivery device 73 can be inserted through a small opening and guided by an endoscope to reattach a tendon 40 back to the humerus 39 without suture sewing, manipulating or tying.

5 Figure 33 shows how a surgeon can use the sleeve 18 to push and position the tendon 40 back to the humerus 39 endoscopically. Similar to the ACL 28 repair indicated in figure 30, the fasteners 13 should be long enough to extend from the hole pierced in the humerus 39 to the tendon 40 tissue. After the tendon 40 has been positioned, the fastener 13 is deployed to anchor the tendon 40 back to the humerus 39. The device operation is similar to that
10 previously described. Multiple fasteners 13 can be deployed to firmly fasten the ruptured tendon 40.

(D) Bulging or herniated disc fastening and repair

Low back pain from bulging or herniated discs 41 is one of the most prevalent, painful and debilitating ailments afflicting mankind. As mentioned, treatments ranging from the
15 traditional to the percutaneous approaches all have their drawbacks, some are very serious. All these approaches have one thing in common: tissue removal. Vastly different from the tissue removing procedures, the methods described herein use various techniques and devices to fasten the bulging or herniated disc 41 to alleviate nerve 25 impingement.

To fasten a bulging or herniated disc 41, the spring-like fasteners 13 of the invention
20 are made extra long with multiple gripping elements 14. Figure 34 depicts a long fastener 13 with a spring-like or shape memory element 15 and multiple gripping elements 14 on both ends. This type of fastener may be suitable for intervertebral use, especially for fastening bulging or herniated discs 41 of the spine.

Figure 35 depicts a nerve retractor 51 lifting an impinged nerve 25 away from a
25 bulging or herniated disc 41. A delivery device 73 is loaded with a fastener 13 similar to the one in figure 34. For the best result, the needle 1 of the fastener delivery device 73 punctures the bulging portion and is guided into the disc 41 by anteroposterior and lateral fluoroscopy or other technique. In cases where the bulging portion of the disc 41 is well concealed by the lamina of the vertebra, a small amount of the bone can be removed to allow penetration of the
30 delivery device 73.

To prevent possible leakage of the nucleus pulposus around the fastener 13, prior to device 73 insertion into the disc 41, an optional sealing patch 43, made with elastic and biocompatible material with closure capability, may be inserted on the needle 1 near the
35 proximal portion of the needle slit 2. For best results, the sleeve 18 is fixed proximally and stationary to provide a position where the proximal tip of the soon to be deployed fastener 13 will grip the sealing patch 43. Using similar guiding, inserting and compressing techniques, the sealing patch 43 is tightly compressed, adhered or maybe even embedded into the previously bulging or herniated annulus 41. As the fastener 13 is deployed, it grips the patch 43 to seal possible leakage of nucleus pulposus.

Figure 36 depicts the compression of the bulging disc 41 and the optional sealing patch 43 around the sleeve 18, when the appropriate depth is reached. While compression continues, the fastener 13 is deployed to grip and compress the previously bulging tissue back in place as shown in figure 37. To make possible the push and hold technique using the sleeve 18 during deployment of the fastener 18, the distal end of the sleeve 18 also contains a slit 19, which overlaps the slit 2 of the needle 1. As the device 73 is set in the in-phase mode, all three slits 2, 8, 19 of the needle 1, cartridge 7 and sleeve 18 are aligned, allowing the fastener 13 to deploy and hold the compressed tissue in place. When applied prior to fastener deployment, the sealing patch 43 is also compressed against the bulging disc 41. The sealing patch 43 is made with elastic and conforming material capable of sealing potential leakage of nucleus pulposus. However, the annulus may be self-sealing with no significant leakage of nucleus pulposus. Therefore, the sealing patch 43 is optional.

Once the device 73 has been withdrawn, as shown in Figure 38, the fastener 13 remains within the disc 41 with constant gripping and fastening forces maintained and substantiated by the spring-like or shape memory element 15, thereby holding back the previously bulging annulus 41.

Similar to previously mentioned surgical procedures, more than one fastener 13 can be deployed through the puncture site 32, preferably toward different directions, to enhance a permanent fastening. The spring-like fasteners 13 with multiple gripping elements 14 provide an exceptionally strong holding strength, away from nerves.

Figure 39 depicts the sealing patch 43 gripped by the proximal portion of the fastener 13 outside the repaired annulus, not shown. The main function of the sealing patch 43 is to prevent possible leakage of the nucleus pulposus. The preferred materials used in constructing the patch 43 are silicone rubber, elastic polymer or biomaterial. Polyurethane or other material can be added or sandwiched to strengthen the sealing patch 43. However, the sealing patch 43 is optional, and the fastener 13 can be deployed entirely within the disc, without protrusion.

For fastening bulging discs 41, devices other than the fastener delivery device 73 can be used. Figure 40 shows an alternate device using a disc fastening screw 44 with variably pitched threads 63 designed to compress and fasten the bulging annulus. The screw 44 may be inserted directly in the disc 41 or a pre-punctured hole may be used. A washer 45 containing a locking nub in conjunction with the locking teeth 64 prevents loosening of the screw 44.

A needle puncturing a bulging disc may be guided by a three-dimensional viewing technique as mentioned, creating an entry for the disc fastening screw 44. After the withdrawal of the needle, the screw 44 enters to fasten the previously bulging disc 41, as shown in Figure 41. The optional sealing patch 43 can be used in conjunction with the screw 44 and washer 45.

Sutures 21 can also be used to fasten a bulging or herniated disc 41. Sutures 21 may be made of natural materials, such as gut, polymers, such as polyester, nylon and PTFE, or metals, such as stainless steel. Figure 42 depicts another bulging or herniated disc fastening device using a suture 21 tied to the midsection of a dumbbell shaped rod 47. The rod 47 with

suture 21 is fitted inside a spinal needle 46. Behind the rod 47, a plunger 48 is inserted into the spinal needle 46. Figure 43 depicts the assembly of the rod 47, suture 21 and plunger 48 inside a spinal needle 46.

Figure 44 depicts a guided puncture using the spinal needle 46 containing the assembly of the rod 47, suture 21 and plunger 48, as indicated in figure 43, through the bulging or herniated disc 41. To avoid potential damage to vessels, nerves or other tissue, the protrusion of the distal tip should be minimal. With the plunger 48, the rod 47 is pushed out of the distal opening of the spinal needle 46, outside the annulus as indicated in Figure 45.

The rod 47 is now caught by the outer surface of the annulus and acts as an anchoring device for the suture 21. The spinal needle 46 is removed, as shown in Figure 46. A washer 49 is threaded with the suture 21, slipped down to the bulging disc 41, compressed and tied. For surgical convenience, the washer 49 can be made in conjunction with a suture-locking device to eliminate suture tying. The thickness of the washer 49 should be minimal to minimize potential contact and irritation of any adjacent nerves. The suture holes in the washer 49 should be as close as possible to avoid substantial spreading of the suture 21. Suture 21 spreading may create a passage for leakage of nucleus pulposus. The optional sealing patch 43 can be used in conjunction with the washer 49.

Figure 47 shows the previously bulging disc 41 compressed by the washer 49 and fastened by a suture knot 50. To avoid potential irritation of the nerve 25 by the suture 21, the exposed suture 21 should be trimmed near the suture knot 50.

Depending on the severity of the bulge or herniation, a simple staple 78 or tack with tissue holding elements may be sufficient to fasten the weak annulus. Figure 48 depicts a staple 78 with annulus-holding barbs 79. For minor bulging, the simple staple 78 may be sufficient to fasten the bulge. If needed, the legs of the staple 78 can be made significantly longer than the ones depicted in the drawing. Figure 49 depicts another type of staple 78 with shape memory legs 80 to hold and fasten a bulging disc 41. The shape memory legs 80 of the staple 78 can also be made significantly longer than the ones depicted in the drawing.

Since the guiding techniques for inserting fasteners into the bulging or herniated discs 41 are similar to the ones used in relatively low risk percutaneous nucleotomy procedures and routine diagnostic discography for determining herniation, the methods used in fastening bulged or herniated discs 41 should also be low in risk and complications.

The depth of the device penetration, the overall length of the fasteners 13, and direction of fastener 13 insertion are related and are very important issues in fastening bulging or herniated discs 41. The nucleus pulposus in the central portion of the discs 41 is unlikely to be effective in gripping. With the information provided by discography or other diagnostic techniques, healthy annulus around the bulge or across the nucleus pulposus can be used to anchor the fasteners. To prevent possible contact between fasteners and nerves 25 or other tissues, protrusion of the deployed fasteners outside the disc 41 is preferred to be minimal or absent. For example, the fastener 13 may be deployed without entirely piercing through the

opposite wall of the disc 41 so that only a single puncture is made, or the fastener 13 may be deployed entirely within the disc 41 such that once the delivery device 73 is removed there are no protrusions from the wall of the disc 41.

Some surgeons may like to approach the disc repair anteriorly. After retracting the abdominal contents, the fastener delivery device 73 can be guided, perhaps by fluoroscope or other means, through the disc 41 to the bulging or herniated portion. As the tip of the device reaches or nears the bulging surface, the distal half of the fastener 13 is deployed. The bulging portion of the disc 41 is gripped and pulled inward, then the fastener 13 is totally deployed to fasten the bulging disc 41. Although the anterior approach is possible, the posterior approach usually reaches the bulge more directly and is preferred.

Unlike the tissue removing approaches of percutaneous nucleotomy, chymopapain digestion or discectomy, fasteners in general directly, actively and/or elastically hold the bulging or herniated tissue back without removing the nucleus pulposus, the essential component to sustain prolonged compression when upright, and resiliently re-inflate and re-establish disc height when at rest. Therefore the bulging or herniated disc 41 may be repaired without loss of the disc 41 or nucleus pulposus.

(E) Urinary or fecal incontinence repair

For the sufferers of urinary or fecal incontinence, the inconvenience and social problems are often too great to ignore, but the treatment options are far from ideal. The options range from ineffective injections to open surgeries with possible serious complications. With options such as these, it is no wonder that over \$400 million is spent each year on adult diapers (Colon, Rectum and Anus, 2nd Ed., Philip Gordon, M.D., et. al., 1999).

Figures 50-54 show the fasteners 13 deployed or being deployed to elastically grip or close passages within the body to alleviate urinary and fecal incontinence. For urinary incontinence, the sphincter urethrae or the urethra itself are possible sites for fastening. For fecal incontinence, the rectal sphincter 54 is a potential site for fastener 13 deployment. Fasteners 13 may also be used to resiliently close the rectum, anal canal or other passages within the body. As the pressure from the bladder 53 or colon increases, the elastically fastened sphincters 54 open to allow passage of contents. After the contents are emptied, the pressure decreases and the sphincters 54 are again elastically closed by the resiliently curved fasteners 13. For patients with no neurological problems, the elastically fastened sphincters 54 may also be opened by voluntary muscles.

Regarding the insertion of the fastener delivery device 73, numerous existing guiding techniques, such as cystoscope, ultrasound, anteroposterior-lateral fluoroscopy, MRI, or others, can be used effectively and accurately to guide the insertion and deployment of the fasteners 13. Again, multiple fasteners 13 can be used to ensure proper closure of the sphincter 54.

Figure 50 depicts an insertion of the fastener delivery device 73 into a leaking anal sphincter 54. When a fastener 13 is deployed, the fastener 13 elastically grips and closes a portion or the entire leaky opening of the sphincter 54.

Figure 51 depicts a deployed fastener 13, indicated by the dotted curvature, around the anal sphincter 54. The device 73 is reinserted into another portion of the sphincter 54 to deliver another fastener 13. Although other orientations may be used, in this example, the device entries are approximately 90° to each other.

Figure 52 depicts an elastic closure of the anal sphincter 54, in this case with two spring-like fasteners 13 under the skin.

Figure 53A depicts a sphincter 54 leaking due to incomplete closure. The sphincter 54 can be urinary or fecal.

Figure 53B depicts the partial closure of the sphincter 54 by a spring-like fastener 13. In this example, the fastener 13 has very few gripping elements 14 to minimize irritation of nerves around the sphincter 54.

Figure 53C depicts the elastic closure of the sphincter 54 by two spring-like fasteners 13.

Especially among elderly patients, the elasticity or the resiliency of the sphincter urethrae and/or the rectal sphincters varies greatly. Before inserting the fastener delivery device 73, elasticity or resiliency sensing instruments can be used to determine the closing pressure of the sphincter prior to selecting fasteners 13 with appropriate gripping forces, closure strengths and curvatures suitable for individual patients.

Figure 54 depicts possible entries for the fastener delivery devices 73 for treating urinary and fecal incontinence. Three-dimensional guiding instrumentation may be required, especially for urinary closure. To provide instant feedback to the surgeon, a pressure sensing catheter balloon, strain gauge, or tightening detecting instrument 55 can be inserted into the leaking portion of the rectum and/or urethra. As the fastener 13 deploys and tightens the leaking portion, the instrument 55 can provide instant information to the surgeon regarding the closing pressure, placement and effectiveness of the deployed fastener 13. As a result of properly deployed fasteners 13, the elastic closure of the urethra and/or anal canal can provide instant and probably long lasting improvement to incontinence problems.

For fluoroscopic image enhancement, the catheter or instrument 55 can be made or coated with radiopaque material to perfect the accuracy of the fastener delivery device 73 insertion. For ultrasound image enhancement, echogenic enhancing material can be used. Similarly, the needle 1 of the fastener delivery device 73 can also be coated with image enhancement material, such as radiopaque, echogenic, etc., for even more accurate device 73 insertion.

The delivery of spring-like fasteners 13 is considered minimally invasive and a low risk procedure. The benefits, however, can be long lasting and comparable to or exceeding the results of open surgery. Furthermore, both the device 73 and the fasteners 13 probably would

not invade the inner lining of the sphincter 54 or contact potentially contaminated waste material. Therefore, infection and other complications may be significantly minimized.

(F) Carpal tunnel syndrome relief

Repetitive strain injuries have become more and more common. A particularly common and debilitating form is carpal tunnel syndrome. Many who suffer from carpal tunnel syndrome depend on their manual dexterity to perform their jobs. Prolonged or frequent restrictions of hand and wrist movement pose significant problems in their job performances. Surgical relief by cutting the flexor retinaculum 57 to decompress the median nerve seems to be too drastic and may lead to complications.

Figure 55 depicts a hand with carpal tunnel syndrome and insertion of a fastener delivery device 73 into the flexor retinaculum 57, not shown under the skin, guided by penetration markers 3 or other devices. The fasteners 13 are deployed within the retinaculum perpendicular to and over the median nerve and toward the palm.. With the elastic curvature of the fastener 13 and the pliable nature of the flexor retinaculum 57, the curvature of the fastener 13 forms the shape of an arch, lifting the flexor 57 tissue, which was compressing the median nerve. Figure 56 depicts several fasteners 13 deployed toward the palm lifting the central portion of the flexor retinaculum 57, creating a tunnel or an arch to accommodate the irritated median nerve without cutting the flexor retinaculum 57. The fasteners 13 can even be made with biodegradable materials, which degrade with time after relieving the pain and inflammation.

(G) Double indented needle slit for versatile tissue manipulation and interlocking fasteners

Depending on the surgical needs, sometimes the proximal half 77 of the fastener 13 can provide better assistance in tissue manipulation than the distal half 76 of the fastener 13. It is possible to open the slit 2 in ways to allow the deployment of either the distal portion 76 or the proximal portion 77 of the fastener 13 in semi-in-phase mode. One side of the slit 2 is indented at the distal half 74 while the other side of the slit 2 is indented at the proximal half 75, as indicated in figure 58. Depending on the direction of cartridge 7 rotation, relative to the needle 1, the semi-in-phase mode can bring out either the distal end 76 or the proximal end 77 of the fastener 13. Tapered fastener holding elements 60 may cover and support both semi-deployments.

To enhance the double indented feature of the needle slit 2, the curvature of the fasteners 13 can be made asymmetrical, as shown in figures 57A and B. For example, the first fastener 13 in the deploy position is made with a curvature near the proximal end 77 of the fastener 13, as shown in figure 57A. The following fastener 13 in the cartridge 7 is made with a curvature near the distal end 76 of the fastener 13, as shown in figure 57B. After semi-deploying the proximal half 77 of the first fastener 13, the tissue is tightened by pushing, then fully deploying the first fastener 13. The device 73 is slightly withdrawn and reset to out-of-phase. The following fastener 13 is advanced into the deploy position. The distal portion 76 of the second fastener 13 is semi-deployed into the tissue. Instead of tissue tightening by pushing as

indicated with proximal deployment, the distal semi-deployment requires pulling of the device 73 to tighten the tissue before full deployment. With tissue tightening by pushing and pulling, the fasteners 13 interlock the tissue, through one needle 1 puncture. Other than pushing and pulling on the semi-deployed fasteners 13, twisting provides yet another dimension and benefit to the tissue manipulation and interlocking fastening.

The double indented needle slit 2 and the fasteners 13 with asymmetrical curvature can be utilized to clamp arteries, restrict sphincters, reattach tissue or other uses.

(H) Tumor artery closure

A tumor 56 demands far more nutrients than normal tissue. Cutting the arterial 23 blood supply may slow the growth or even diminish the size of a tumor 56 prior to surgical removal. With an angiogram, the location of the arteries 23 supplying the tumor 45 is mapped out. Figure 59 depicts the fastener delivery device 73 inserted and guided to a tumor-feeding artery 23. With the needle slit 2 facing the artery 23, the proximal portion 77 of the fastener 13 is deployed under the artery 23. The device 73 may then be gently pushed to compress and restrict the artery 23. While pushing, the fastener 13 is fully deployed to clamp and restrict the artery 23.

Figure 60 depicts the fully deployed fastener 13 from the proximal semi-deployment. The device 73 is slightly withdrawn, reset and advanced with another fastener 13 from the cartridge 7. The second fastener 13 is semi-distally deployed over the artery 23. The device 73 may then be gently pulled to hook and further restrict the artery 23. While pulling, the second fastener 13 is fully deployed to shut the blood flow. More fasteners 13 can be deployed to ensure a complete closure of the artery 23 feeding the tumor 56.

Figure 61 depicts both fully deployed inter-locking fasteners 13 restricting blood flow to the tumor 56. In this example, the figures indicate pushing and pulling actions of the device to restrict the vessel. Twisting or rotating the semi-deployed fasteners 13 to create kinks on the vessels can also provide exceptional closure of the vessel. Also, more fasteners 13 can be deployed along the artery 23.

(I) Additional embodiments

Fasteners 13 are frequently used in or near joints, tendons 40, ligaments or sphincters 54, where tissue movements are routine. Movement can shift the fastener and cause it to migrate. Fastener migration is rarely desirable. In fact, it can be quite damaging, especially when the fastener migrates into joints, nerves 25 or vessels. For sphincter 54 repair, migration can negate the corrected closure of the dysfunctional sphincter 54.

Figure 62 depicts a fastener 13 with tissue ingrowth holes 4 to minimize possible fastener 13 migration. The holes 4 can also be in the flexible or shape memory element 15.

Figure 63 depicts another fastener 13 with tissue ingrowth grooves 5 designed to minimize fastener 13 migration. The grooves 5 can also be in the flexible or shape memory element 15.

Figure 64 depicts a suture 21 attached to a fastener 13 with gripping elements 14 and spring-like or shape memory element 15. The fastener 13 can be used as a suture anchor, holding the suture 21 for tissue attachment. This type of suture anchor can be used for cosmetic surgery with minimal incision.

5 The fastener delivery device 73 utilizes the rotating cartridge 7, relative to the needle 1, to deploy fasteners 13 into tissue through overlapping slits 2, 8. Similar fasteners 13 can be resiliently straightened in a spinal needle 46 without the cartridge 7. Instead, a plunger 48 is fitted inside the spinal needle 46 behind the fastener 13, as shown in figure 65. After insertion of the needle 46 into tissue, the plunger 48 is held stationary while the needle 46 is slowly
10 retracted or withdrawn from tissue, thereby deploying the fastener 13 out of the distal opening of the needle 46. In tissue, the fastener 13 resumes the original resilient curvature and tightly fastens onto the tissue. Multiple fasteners 13 can also be loaded into the needle 46 and deployed one at a time into different locations.

Figure 66 depicts an exploded view and figure 67 an assembled view of a modular
15 fastener 13. The modular gripping elements 14 mount into optionally recessed areas or pockets of a fastener 13 secured by stems 71, which tightly fit into gripping element holes 72. Due to the pressure exerted by the spring-like or shape memory element 15, the modular gripping elements 14 are not free to be lifted off from the main fastener body in the delivery device 73 or in tissue after deployment.

20 Modular gripping elements 14 can be extremely useful in some surgical repairs. For example, anal sphincter 54 fastening for fecal incontinence may adversely affect nerves 25 and blood vessels surround anal sphincters 54. It may be difficult to fasten just the nerve-free portion of the sphincter 54. The gripping elements 14 of the fastener 13 may irritate nerve
25 fibers after the deployment of the fasteners 13. However, the gripping elements 14 are essential for anchoring the long-lasting fasteners 13 in place. With biodegradable modular gripping elements 14, the elements 14 degrade away after the fasteners 13 have been secured and tissues have grown into the tissue ingrowth holes 4 or grooves 5 (as shown in figure 63). Irritation of the nerve is then minimized with the remaining portion of the long-lasting elastic fasteners 13 gripping the sphincter 54.

30 For other surgical purposes, instead of relying on the gripping elements 14 to secure the fastener 13, the modular portion of the gripping elements 14 can be replaced with high friction coefficient materials such as silicone rubber or with tissue adhesives.

Figure 68 depicts a needle slit 2 formed with a smooth and round curvature to minimize puncture resistance. With clockwise cartridge 7 rotation, the depicted smooth
35 indentation accommodates distally semi-deployed fastener 13.

Figure 69 depicts a needle slit 2, which is slanted. As the cartridge 7 and fastener 13, both not shown, rotate counter-clockwise, the distal portion of the fastener 13 would initially deploy out of the slanted needle slit 2. For clockwise rotation, both distal and proximal portions protrude out of the needle 1 while the middle portion of the fastener 13 remains in the

needle 1. With tissue gripping by both distal and proximal portions of the fastener 13, extra tissue manipulative power is provided to the surgeon prior to complete fastener deployment.

Figure 70 depicts an exploded view and figure 71 an assembled view of a modular fastener 13. The modular arm 67 has a connecting stud 69 extending from the end. A connecting hook 70 also extends from the modular arm 67 adjacent the connecting stud 69. The connecting stud 69 and connecting hook 70 are placed within a connecting hole 68 within the shape memory element. The connecting hook 70 extends into a mating locking notch within the connecting hole 68, thereby locking the parts of the modular fastener 13 together.

Modular arms 67 can provide benefits which a single piece fastener 13 may not cover, especially when the arms 67 are made with different materials, size, shape, curvature, physical treatment or others. For example, the bulging portion of the annulus requires extra tension from the fastener 13 to retain the bulge. If the whole fastener 13 were made with a high tensile strength material, the whole disc would be adversely pinched out of shape by the fastener 13. However, with modular capabilities, the bulge-retaining arm 67 can be made with high tensile strength material while the anchoring arm is made with a lower strength material. As a result, the bulging annulus is retained without pinching the entire disc.

For tissue attachments into thin bones, insertion of permanent fasteners 13 can weaken the bone and may even cause future fracture from excessive load. To prevent bone weakening, biodegradable arms 67 and gripping elements 14 can be used to insert into bones, while the remaining portion of the fasteners 13 can be made with strong and permanent material.

To optimize fastening capability in some special surgical repairs, one arm 67 can be made with elastic material and the other arm 67 can be made with shape memory material.

For fasteners 13 made with a significant curvature, modular components or composition may relieve the strain of the fastener 13.

Modular components, such as the gripping elements 14, arms 67 and spring-like or shape memory element 15, of a fastener 13 can provide numerous benefits and greatly improve fastening performance. The components can be made with different materials, curvature, degradability, biocompatibility, hardness, tensile strength, tensile modulus, modulus of elasticity, size, friction coefficient, transition temperature, transformation temperature, torsion, other physical, chemical or biological characteristics. In addition to the depicted connecting means for assembling the modular components, numerous other methods and configurations can be used for a functional fastener 13.

Figure 72 shows the back line 66, indicated by dots, as the other orientation line on the needle 1 which indicates direction of the back of the deploying fastener 13.

Figure 73 depicts a curved needle 1. For hard to reach repair sites, a curved needle 1 can allow the surgeon to access and fasten the repair site hidden behind or around adjacent tissues. Similarly, a curved needle 1 can penetrate under the skin or tissue for fastening or closure.

To accommodate cartridge 7 rotation in the curved needle 1, flexible metal, such as nickel-titanium, or flexible polymer can be used to construct the cartridge 7. Other embodiments could use a counterwound or braided torque cable.

(J) Retrieval of deployed fastener

5 As with any other surgical procedure, mistakes can occur with fastener 13 deployment. Fortunately, the deliveries of fasteners 13 described in this invention are minimally invasive. As long as the incorrectly deployed fastener 13 does not pose problems or cause discomfort to the patient, the incorrectly deployed fastener 13 can be left in place. After learning from the error, one can then correctly deploy another fastener 13.

10 Some incorrectly deployed fasteners 13 can cause problems for the patients; those fasteners 13 should be removed. The best way to remove the sustained gripping fastener 13 is to endoscopically cut the mid-section of the fastener 13 before pulling each section out of the patient. If the retrieval of the problematic fastener 13 is too difficult or even impossible through an endoscopic approach, an open surgery may be necessary. Although incorrect
15 deployment happens, the fasteners 13 and the delivery devices 73 mentioned in this invention provide superior control for the surgeons during the procedures and outstanding results for the patients when the fasteners 13 are properly deployed.

(K) Accessibility of the fastener delivery device

In addition to the sustained gripping property of the fastener 13 and the versatility of the
20 delivery device 73, another major benefit to this invention is that with proper guiding techniques, the device 73 can deliver the fasteners 13 deep into the body of the patient. The needle 1 of the device 73 can be curved with a flexible cartridge 7 to accommodate rotation within the curved needle 1 to reach around organs and tissue into a target site.

Many other surgical procedures can utilize the fastener 13 and the delivery device 73.
25 Some examples follow. The fastener 13 and delivery device 73 can endoscopically attach dislocated organs. For weight loss purposes, fasteners 13 can be used to slow stomach emptying by restricting the pyloric sphincter or pyloric canal. The fasteners 13 can also be used to attach medical devices inside the body.

The fastener 13 and the delivery device 73 can serve in numerous endoscopic
30 procedures, which require connecting, reattaching, holding, fortifying, restricting, closing, compressing or decompressing tissues or other devices.

In brief summary, the possible benefits of the sustained gripping fasteners 13 and the delivery device 73 include: (1) grip tissue continuously, (2) minimize fastener migration, (3) minimally invasive, (4) deploy multiple fasteners within a puncture site, (5) access deep body
35 targets, (6) support and fortify fragile tissue, (7) reattach tissue without suturing, (8) attach tissue to bone, (9) require minimal surgical space, (10) attach to other fastening devices, (11) versatile, (12) provide permanent and/or degradable fastening, (13) simple to use, (14) manipulate tissue, (15) restrict or close orifices or vessels, (16) compress or decompress tissue, and (17) provide directional fastening.

(L) Materials and designs

The needle 1 of the fastener delivery device 73 is preferred to be made with stainless steel. Other alloys, metals, polymers, graphite composites, ceramics, or other materials can also be used. For tissue puncturing, the distal opening 16 of the needle 1 is sharpened or shaped into various configurations appropriate for the need. Normally, the needle 1 is made straight. But for hard-to-reach surgical sites, the needle 1 can be made curved with a flexible cartridge 7 to accommodate rotation in the curved needle 1. Penetration markers 3, a deploy line 65 and a back line 66 can be printed or etched on the surface of the needle 1. Lubricating coatings, such as silicone oil, plasma coating, PTFE or others, can be applied inside the needle 1 to decrease friction during the operation of the fastener delivery device 73. The lubricious coatings can also be used on the outside of the needle 1 to ease the tissue penetration.

To enhance the guiding capabilities of the needle 1 into tissue, the needle 1 can be coated with radiopaque, ultrasound echoing or other image-enhancing material.

The needle body 61, handle 6 and cartridge cap 58 can be made with polymers, metals, other materials or combinations thereof.

Stainless steel is the preferred material for making the sleeve 18, although other materials, such as polymers or other metals can be used. To fit over the curved needle 1, flexible materials, such as nickel titanium or polymers, are more suitable materials for making the sleeve 18. Likewise, the sleeve handle 20 can also be made with stainless steel, polymers or other metals.

Similar to the preferred material used for making the needle 1, the cartridge 7 is also preferred to be made with stainless steel, but materials, such as other metals, polymers, graphite composites, ceramics or others, can also be used. If the needle 1 is curved, the cartridge 7 material should be flexible enough to accommodate the rotation in the curved needle 1. Nickel titanium alloy is a strong and flexible metal, which may be suitable for making the flexible cartridge 7.

Both slits 2, 8 of the needle 1 and cartridge 7 are wider than the width of the fasteners 13. The length of the cartridge slit 8 may differ from the length of the needle slit 2. In fact, the length of the cartridge slit 8 can open longitudinally along the cartridge 7, as a trough. The open trough may provide several major benefits. The trough can serve as railings to align and maintain the fasteners 13 to face a certain direction. The opening of the trough provides more space to decrease stress and strain on the resiliently straightened fasteners 13, and it accommodates larger fasteners 13, which otherwise would not fit in a tube-like cartridge 7. The length and configuration of the cartridge slit 8 can be further modified depending on the material used to construct the cartridge 7 and on the requirement of the fasteners 13. A lubricious coating can be applied especially on the inside wall of the cartridge 7 to decrease friction during advancement of the fasteners 13.

The simple fastener-advancing unit consists of a plunger 10 driven by screw action of the advancing device 11 with a handle 12. Ideally, the pitch of the screw is spaced out

precisely so that each turn or half a turn on the handle 12 advances a fastener 13 into the deploy position. Other advancing devices and mechanisms can also be used. The material used in the fastener-advancing device can be metal, polymer, ceramic or combinations of these.

5 The fastener delivery device 73 can come conveniently loaded with one or more fasteners 13 in the cartridge 7 chamber. However, with some mechanical or temperature assistance, it is not prohibitively difficult to load fasteners 13 into the cartridges 7 in the surgical room.

10 It should be clear to one skilled in the art that the current embodiments, methods and surgical sites are not the only uses for which the invention may be used. Different materials for the needles, cartridge, bodies, handles, fasteners and other components can be used. The use of this invention is also foreseen to repair, fasten, close or restrict various tissues, such as canals, organs, vessels, tendons, ligaments, muscles, cartilage, skin, bone, valves, prostheses, cosmetic lifts, tissue grafting, and other surgical procedures. Nothing in the preceding description should be taken to limit the scope of the present invention. The full scope of the
15 invention is to be determined by the appended claims.

APPENDIX A
NUMERICAL REFERENCES IN DRAWINGS

Needle	1
Slit of needle	2
Penetration markers	3
Tissue ingrowth hole	4
Tissue ingrowth groove	5
Needle handle	6
Cartridge	7
Slit of cartridge	8
Cartridge handle	9
Fastener-advancing plunger	10
Fastener-advancing device	11
Fastener-advancing handle	12
Fastener	13
Gripping elements	14
Spring-like or shape memory element	15
Needle distal opening	16
Cartridge distal opening	17
Sleeve	18
Slit of sleeve	19
Sleeve handle	20
Suture	21
Torn tissue	22
Artery	23
Vein	24
Nerve	25
Meniscus	26
Capsule	27
Anterior cruciate ligament, ACL	28
Ligament holder	29
Device guiding tracks	30
Ligament holder handle	31
Puncture site	32
Trocar	33
Cannula	34
Drill	35
Bone stop	36

Cannula stop	37
Bone	38
Humerus	39
Tendon	40
Bulging or herniated disc	41
Spinal cord	42
Sealing patch	43
Screw	44
Washer with locking snub	45
Spinal needle	46
Dumbbell shaped rod	47
Plunger	48
Washer	49
Suture knot	50
Nerve retractor	51
Anus	52
Bladder	53
Sphincter	54
Tightening detecting instrument	55
Tumor	56
Flexor retinaculum	57
Cartridge cap	58
Sleeve-sliding track	59
Tapered fastener holding elements	60
Needle Body	61
Cartridge body	62
Variable pitch thread	63
Locking teeth	64
Deploy line	65
Back line	66
Arm	67
Connecting hole	68
Connecting stud	69
Connecting hook	70
Gripping element stem	71
Gripping element hole	72
Fastener delivery device	73
Distal portion of needle slit	74

Proximal portion of needle slit	75
Distal portion of fastener	76
Proximal portion of fastener	77
Staple	78
Barbs on staple	79
Shape memory staple legs	80
Ligament holding device	81

We claim:

- 1 1. A fastener for gripping tissue, the fastener comprising:
2 a fastener having a first end, a second end and a middle portion,
3 a plurality of gripping elements located on said first end of said fastener, at least a portion
4 of said fastener being formed of a resilient material, said resilient material
5 predisposing said fastener to form a curved or bent shape,
6 said fastener having an open position and a closed position,
7 wherein in said open position, said fastener is configured to pass through a generally
8 cylindrical passage,
9 wherein in said closed position, said fastener assumes said curved shape, said gripping
10 elements located on a concave side of said fastener when said fastener is in said
11 closed position, thereby grasping the tissue between said gripping elements.
- 1 2. The fastener of claim 1 wherein said resilient material is predisposed to form said fastener
2 into a curve at a temperature at or below body temperature.
- 1 3. The fastener of claim 1 wherein said gripping elements are a plurality of generally parallel
2 grooves running across said concave side of said fastener.
- 1 4. The fastener of claim 1 wherein said fastener further comprises at least one tissue ingrowth
2 hole passing therethrough.
- 1 5. The fastener of claim 1 wherein said fastener further comprises at least one tissue ingrowth
2 groove carved out of a side of said fastener
- 1 6. The fastener of claim 1 further comprising a suture and a suture opening passing through
2 said fastener, said suture passing through said suture opening.
- 1 7. The fastener of claim 1 wherein said second end of said fastener has a plurality of gripping
2 elements.
- 1 8. The fastener of claim 1 wherein said entire fastener is formed of said resilient material.
- 1 9. The fastener of claim 1 wherein said resilient material is a shape memory material.
- 1 10. The fastener of claim 9 wherein said shape memory material is a nickel titanium alloy.

- 1 11. The fastener of claim 9 wherein said shape memory material predisposes said fastener to
2 bend such that said first-end has a greater degree of curvature than said second end.
- 1 12. The fastener of claim 1 wherein said fastener is a modular fastener and is formed from a
2 first piece including said first end and a second piece including said second end.
- 1 13. The modular fastener of claim 12 further comprising a third modular piece including said
2 middle portion.
- 1 14. The modular fastener of claim 13 wherein said first piece and said second piece consist of
2 said gripping elements and are biodegradable.
- 1 15. The fastener of claim 1 wherein said fastener is configured to grip the tissue without
2 piercing the tissue to be grasped.
- 1 16. The fastener of claim 1 wherein said fastener has ends configured to grasp the tissue
2 without puncturing.
- 1 17. The fastener of claim 1 wherein said fastener has a length between 1.0 mm and 200 mm
2 and a width between 0.1 mm and 30 mm.
- 1 18. The fastener of claim 1 wherein said fastener has a length between 3.0 mm and 70 mm
2 and a width between 0.5 mm and 7.0 mm.
- 1 19. A fastener delivery device for delivering a resilient fastener, comprising:
2 a hollow, tubular needle having a distal end, a proximal end and a passage extending
3 therethrough and a slit extending through a side thereof,
4 a handle coupled with said needle,
5 and a fastener deployment actuator coupled with said needle.
- 1 20. The fastener delivery device of claim 19 further comprising a plurality of tapered fastener
2 holding elements located within said needle proximate said slit.
- 1 21. The fastener delivery device of claim 19 wherein said needle has a plurality of grooves
2 within said needle and extending from at least one side of said slit wherein said plurality of
3 grooves are sized to engage a plurality of gripping elements on the resilient fastener.

1 22. The fastener delivery device of claim 19 wherein said slit has a first side and a second side
2 and an interior surface of said needle has a plurality of sloped grooves extending to said first
3 and second sides of said slit.

1 23. The fastener delivery device of claim 19 further comprising a fastener-holding cartridge
2 located within said needle.

1 24. The fastener delivery device of claim 23 wherein said cartridge has a generally U-shaped
2 cross section.

1 25. The fastener delivery device of claim 23 wherein said cartridge has a slit in a side thereof,
2 said slit extending from a distal end thereof.

1 26. The fastener delivery device of claim 25 wherein said slit in said cartridge extends along a
2 full length of said cartridge.

1 27. The fastener delivery device of claim 23 wherein said cartridge has an opening at a distal
2 end thereof.

1 28. The fastener delivery device of claim 23 wherein said cartridge is rotatable within said
2 needle.

1 29. The fastener delivery device of claim 23 wherein said cartridge has an in-phase position
2 and an out-of-phase position, wherein in said out-of-phase position said cartridge closes said
3 slit in said needle, and wherein in said in-phase position said slit in said needle is open.

1 30. The fastener delivery device of claim 19 wherein said slit in said needle has two straight,
2 generally parallel edges.

1 31. The fastener delivery device of claim 19 wherein said slit in said needle has a first edge
2 and a second edge, wherein said first edge is substantially straight and said second edge has a
3 step therein, said step creating a first region and a second region, said second region having a
4 greater width than said first region.

1 32. The fastener delivery device of 31 wherein said second region extends from said distal end
2 of said needle and said first region is proximal to said second region.

1 33. The fastener delivery device of claim 19 wherein said slit in said needle has a first edge
2 and a second edge, wherein said first edge and said second edge each have a step therein, said

3 steps creating a first region and a second region, said second region being offset from said first
4 region.

1 34. The fastener delivery device of claim 33 wherein said slit has a plurality of grooves located
2 both proximal to and distal to at least one of said steps in said slit.

1 35. The fastener delivery device of claim 33 wherein said step in said first edge and said step
2 in said second edge are substantially equal such that said first region and said second region
3 have approximately equal widths.

1 36. The fastener delivery device of claim 19 wherein said slit has a first substantially straight
2 edge and a second substantially straight edge and wherein said first edge and said second edge
3 are nonparallel.

1 37. The fastener delivery device of claim 36 wherein said slit is wider at a distal end of said slit
2 than at a proximal end of said slit.

1 38. The fastener delivery device of claim 19 wherein said slit has a first edge and a second
2 edge and wherein said first and second edges are generally parallel to one another and
3 nonparallel to a longitudinal axis of said needle such that said slit is slanted along said needle.

1 39. The fastener delivery device of claim 19 further comprising a plurality of penetration
2 markings located on said needle.

1 40. The fastener delivery device of claim 19 further comprising a first orientation line along a
2 length of said needle.

1 41. The fastener delivery device of claim 40 wherein said first orientation line has a first visual
2 appearance, said fastener delivery device further comprising a second orientation line opposite
3 said first orientation line and having a second visual appearance, said first and second visual
4 appearances being distinct.

1 42. The fastener delivery device of claim 19 further comprising a protective sleeve locatable
2 around said needle.

1 43. The fastener delivery device of claim 42 wherein said protective sleeve further comprises a
2 tissue manipulation element located on a distal end thereof.

- 1 44. The fastener delivery device of claim 42 further comprising a sliding track along said
2 needle and wherein said protective sleeve moves along said sliding track.
- 1 45. The fastener delivery device of claim 19 in combination with a ligament holder having at
2 least one guide opening sized to receive said needle.
- 1 46. The fastener delivery device of claim 19 further comprising a fastener advancement
2 plunger extending through a proximal portion of said needle.
- 1 47. The fastener delivery device of claim 19 further comprising a coating on a surface of said
2 needle.
- 1 48. The fastener delivery device of claim 47 wherein said coating is lubricious.
- 1 49. The fastener deliver device of claim 48 wherein said lubricious coating is chosen from the
2 group of lubricious coatings including silicone oil, plasma coating and polytetrafluoroethylene
3 (PTFE).
- 1 50. The fastener delivery device of claim 47 wherein said coating is image enhancing.
- 1 51. The fastener deliver device of claim 50 wherein said image enhancing coating is chosen
2 from the group of image enhancing coatings including radiopaque and ultrasound echoing
3 coatings.
- 1 52. The fastener delivery device of claim 19 wherein said needle is curved.
- 1 53. The fastener delivery device of claim 52 further comprising a flexible cartridge.
- 1 54. A fastener delivery system, comprising:
2 a fastener delivery device, including:
3 a hollow, tubular needle having a distal end, a proximal end and a passage
4 extending therethrough and a slit extending through a side thereof,
5 a handle coupled with said needle,
6 and a fastener deployment actuator coupled with said needle,
7 and a resilient fastener loaded within said needle.
- 1 55. The fastener delivery system of claim 54 wherein said slit in said needle is at least as wide
2 as said resilient fastener.

- 1 56. The fastener delivery system of claim 54 wherein said fastener is symmetrically curved.
- 1 57. The fastener delivery system of claim 54 wherein said fastener is asymmetrically curved.
- 1 58. The fastener delivery system of claim 54 wherein said fastener is made of a polymer.
- 1 59. The fastener delivery system of claim 54 wherein said fastener is made of metal.
- 1 60. The fastener delivery system of claim 54 wherein said fastener is biodegradable.
- 1 61. The fastener delivery system of claim 54 wherein said fastener is connected to a fastening
2 device.
- 1 62. The fastener deliver system of claim 61 wherein said fastening device is a suture.
- 1 63. The fastener delivery system of claim 54 wherein said fastener has an opening.
- 1 64. The fastener delivery system of claim 63 wherein said opening passes through said
2 fastener and has a suture located therethrough.
- 1 65. The fastener delivery system of claim 63 wherein said opening is a tissue ingrowth hole
2 extending through said fastener.
- 1 66. The fastener delivery system of claim 63 wherein said opening is a tissue ingrowth groove
2 cut out of a side of said fastener.
- 1 67. The fastener delivery system of claim 54 wherein said fastener contains a substance
2 chosen from the group of substances consisting of lubricants, biocompatible coatings,
3 antibiotics, growth factors, tissue sealing materials, hydrophilic materials, hydrophobic
4 materials, drugs, drug releasing substances, swellable components, coatings and plasma
5 coatings.
- 1 68. The fastener delivery system of claim 54 wherein said fastener delivery device is loaded
2 with a plurality of said resilient fasteners.
- 1 69. The fastener delivery system of claim 54 wherein said fastener is combined with at least
2 one additional fastener to form a generally circular first ring thereby fortifying the tissue.

- 1 70. The fastener delivery system of claim 69 further comprising at least one ring-engaging
2 fastener passing through said first ring and engaging therewith.
- 1 71. The fastener delivery system of claim 70 wherein an end of said ring-engaging fastener
2 engages a bone.
- 1 72. The fastener delivery system of claim 69 further comprising a generally circular second
2 ring formed of at least two fasteners.
- 1 73. The fastener delivery system of claim 72 further comprising at least one ring-engaging
2 fastener passing through and engaging said first and second rings.
- 1 74 The fastener delivery system of claim 54 further comprising a fastener-holding cartridge
2 located within said needle.
- 1 75. The fastener delivery device of claim 74 wherein said cartridge has a slit in a side thereof,
2 said slit extending from a distal end thereof.
- 1 76. The fastener delivery device of claim 74 wherein said cartridge is rotatable within said
2 needle.
- 1 77. A fastener delivery device for delivering a resilient fastener, comprising:
2 needle means for piercing tissue, said needle means have a slit along a side thereof;
3 cartridge means for holding at least one of the resilient fasteners constrained in an
4 extended, open position,
5 handle means for holding and manipulating said fastener delivery device,
6 and deployment means for deploying the resilient fastener through said slit.
- 1 78. The fastener delivery device of claim 77 further comprising advancement means for
2 advance the resilient fastener into a position ready for deployment.
- 1 79. The fastener delivery device of claim 77 wherein said deployment means deploys a first
2 end of the fastener prior to deploying a second end of the fastener, thereby allowing the user to
3 manipulate the surrounding tissue by moving the fastener.
- 1 80. The fastener delivery device of claim 77 used in combination with a plurality of the
2 resilient fasteners, said resilient fasteners having gripping means for gripping tissue into which
3 said resilient fasteners are deployed.

1 81. The fastener delivery device of claim 77 further comprising tissue manipulation means for
2 moving the tissue during use of said fastener delivery device.

1 82. The fastener delivery device of claim 81 wherein said tissue manipulation means includes
2 a sleeve located around said needle means.

1 83. The fastener delivery device of claim 77 wherein said slit in said needle means has a first
2 edge and a second edge, wherein said first edge and said second edge each have steps therein,
3 said steps creating a first region and a second region, said second region being offset from said
4 first region.

1 84. A method of delivering a resilient fastener into human or animal tissue, the method
2 comprising the steps of:

- 3 (a) inserting a needle into tissue, said needle having at least one resilient fastener
- 4 constrained in an extended, open position therein;
- 5 (b) deploying said resilient fastener into the tissue;
- 6 (c) causing said resilient fastener to move towards a predisposed clamping position;
- 7 (d) and withdrawing said needle.

1 85. The method of claim 84 wherein step (c) is accomplished by releasing said resilient
2 fastener from its constrained condition, thereby allowing it to assume said predisposed
3 clamping position.

1 86. The method of claim 84 wherein step (c) is accomplished by elevating the temperature of
2 the resilient fastener towards body temperature.

1 87. The method of claim 84 wherein said constrained condition is created by mechanical
2 restraint of said fastener delivery device while said resilient fastener is located within said
3 needle.

1 88. The method of claim 84 wherein step (b) is accomplished by:

- 2 (i) deploying a first end of the fastener;
- 3 (ii) and separately deploying a second end of the fastener.

1 89. The method of claim 88 further comprising the step of:

- 2 (iii) manipulating the tissue by moving the fastener between step (i) and step (ii).

1 90. The method of claim 89 wherein said first end of the fastener is a distal end and the tissue
2 is manipulated by pulling the fastener.

1 91. The method of claim 90 further comprising the steps of:

- 2 (e) deploying a second end of a second fastener;
- 3 (f) manipulating the tissue by pushing the second fastener;
- 4 (g) and deploying a first end of the second fastener.

1 92. The method of claim 89 wherein said first end of the fastener is a proximal end and the
2 tissue is manipulated by pushing the fastener.

1 93. The method of claim 92 further comprising the steps of:

- 2 (e) deploying a second end of a second fastener;
- 3 (f) manipulating the tissue by pulling said second fastener;
- 4 (g) and deploying a first end of said second fastener.

1 94. The method of claim 84 wherein the fastener is deployed by rotating a cartridge within
2 said needle to an in-phase position thereby aligning a slit in said needle with a slit in said
3 cartridge.

1 95. The method of claim 94 further comprising the steps of:

- 2 (e) rotating said cartridge to an out-of-phase position, thereby placing said slit in said
3 needle and said slit in said cartridge out of alignment;
- 4 (f) and advancing a following fastener to a position ready for deployment.

1 96. The method of claim 95 further comprising the steps of:

- 2 (g) rotating the needle within the tissue;
- 3 (h) and deploying the following fastener.

1 97. The method of claim 96 wherein steps (e) through (h) are repeated until the tissue is
2 secure.

1 98. The method of claim 84 wherein the fastener is deployed by rotating said needle around a
2 cartridge located therewithin to an in-phase position, thereby aligning a slit in said needle with a
3 slit in said cartridge.

1 99. The method of claim 84 further comprising the steps of:

- 2 (e) reinserting the needle to a new tissue location;
- 3 (f) and deploying a following fastener.

1 100. The method of claim 99 wherein steps (e) and (f) are repeated until the tissue is secure.

- 1 101. The method of claim 84 wherein said fastener is deployed to repair damage to a
2 meniscus.
- 1 102. The method of claim 101 wherein said fastener is deployed entirely within the meniscus.
- 1 103. The method of claim 101 wherein step (b) is accomplished by:
2 (i) deploying a first end of said fastener;
3 (ii) moving a torn portion of the meniscus back towards a pre-damaged position;
4 (iii) and deploying a second end of said fastener.
- 1 104. The method of claim 103 wherein movement of the torn portion of the meniscus is
2 accomplished by pulling said needle.
- 1 105. The method of claim 103 wherein movement of the torn portion of the meniscus is
2 accomplished by pushing said needle.
- 1 106. The method of claim 84 wherein a plurality of fasteners are deployed in a single tissue
2 puncture by said needle, thereby securing the tissue.
- 1 107. The method of claim 84 wherein said fastener is deployed to repair damage to a ligament
2 or tendon.
- 1 108. The method of claim 107 wherein said fastener is a first generally semicircular fastener
2 and the method further comprises the step of:
3 (e) deploying a second generally semicircular fastener opposite said first fastener
4 thereby creating a first ring.
- 1 109. The method of claim 108 further comprises the step of:
2 (f) deploying at least one elongated fastener through said first ring.
- 1 110. The method of claim 108 further comprising the step of:
2 (f) deploying a third and a fourth generally semi-circular fastener to form a second
3 ring.
- 1 111. The method of claim 110 further comprising the step of:
2 (f) deploying at least one elongated fastener through said first and second rings.

1 112. The method of claim 107 wherein said fastener is a first ligament supporting fastener and
2 the method further comprises the step of:

3 (e) deploying a second ligament supporting fastener opposite said first fastener thereby
4 forming a first ligament support fortifying and tying fibers of the ligament.

1 113. The method of claim 112 further comprising the step of:

2 (f) deploying at least one generally linear fastener through said first ligament support.

1 114. The method of claim 112 further comprising the step of:

2 (f) deploying a third and fourth ligament supporting fastener to form a second
3 ligament support.

1 115. The method of claim 114 further comprising the step of:

2 (g) deploying at least one generally linear fastener through said first and second
3 ligament supports.

1 116. The method of claim 107 wherein said fastener is deployed to attach tissue to bone, the
2 method further comprising the steps of:

3 (e) piercing the bone to create an opening;

4 (f) and deploying said fastener such that one end of the fastener is located within the
5 opening in the bone.

1 117. The method of claim 116 wherein the needle has a sharp tip and the bone is pierced by
2 the sharp tip of the needle.

1 118. The method of claim 116 wherein a trocar is used to pierce the bone.

1 119. The method of claim 116 wherein the bone is pierced by drilling a hole in the bone.

1 120. The method of claim 84 wherein said fastener is deployed to repair a bulging or herniated
2 intervertebral disc.

1 121. The method of claim 120 further comprising the step of:

2 (e) passing said needle through the intervertebral disc;

3 (f) compressing the bulge of the intervertebral disc;

4 (g) and deploying said fastener such that a first end of the fastener extends from one
5 side of the intervertebral disc and a second end grips the bulge thereby holding the
6 compression of the bulge.

1 122. The method of claim 121 wherein said second end at least partially extends from another
2 side of said intervertebral disc.

1 123. The method of claim 121 wherein when said needle passes through the bulging or
2 herniated intervertebral disc, and said needle creates an opening, the method further comprising
3 the step of:

4 (h) deploying a sealing member to seal the opening in the bulging or herniated
5 intervertebral disc.

1 124. The method of claim 123 further comprising the step of:

2 (i) deploying a second sealing member to seal a second opening created at a distal end
3 of the fastener.

1 125. The method of claim 84 wherein said fastener is deployed in a sphincter urethrae to
2 reduce urinary incontinence.

1 126. The method of claim 125 further comprising the steps of:

2 (e) checking the closing pressure of the sphincter urethrae prior to deployment of the
3 fastener;

4 (f) and checking the closing pressure of the sphincter urethrae after deployment of the
5 fastener.

1 127. The method of claim 125 wherein the fastener strength is chosen after the resiliency of
2 the sphincter urethrae has been checked.

1 128. The method of claim 84 wherein said fastener is deployed to at least partially and
2 resiliently close a urethra leading from a bladder of a patient.

1 129. The method of claim 128 further comprising the steps of:

2 (e) checking the closing pressure of the urethra prior to deployment of the fastener;

3 (f) and checking the closing pressure of the urethra after deployment of the fastener.

1 130. The method of claim 128 further comprising the steps of:

2 (e) checking the resiliency of the urethra prior to deployment of the fastener;

3 (f) and checking the resiliency of the urethra after deployment of the fastener.

1 131. The method of claim 84 wherein said fastener is deployed in a rectal sphincter to reduce
2 fecal incontinence.

- 1 132. The method of claim 131 further comprising the steps of:
2 (e) checking the closing pressure of the rectal sphincter prior to deployment of the
3 fastener;
4 (f) and checking the closing pressure of the rectal sphincter after deployment of the
5 fastener.
- 1 133. The method of claim 131 further comprising the steps of:
2 (e) checking the resiliency of the rectal sphincter prior to deployment of the fastener;
3 (f) and checking the resiliency of the rectal sphincter after deployment of the fastener.
- 1 134. The method of claim 133 wherein the fastener strength is chosen after the resiliency of
2 the rectal sphincter has been checked.
- 1 135. The method of claim 84 wherein said fastener is deployed to resiliently close a rectum or
2 anal canal leading from a colon of a patient.
- 1 136. The method of claim 84 wherein said fastener is deployed to alter a tissue's shape.
- 1 137. The method of claim 136 wherein said fastener is deployed to relieve a repetitive strain
2 injury.
- 1 138. The method of claim 136 wherein said fastener is deployed to relieve carpal tunnel
2 syndrome.
- 1 139. The method of claim 138 wherein said fastener is deployed within a patient's flexor
2 retinaculum, thereby increasing the arch of the flexor retinaculum to relieve pressure on the
3 median nerve.
- 1 140. The method of claim 84 wherein said fastener is deployed to close or compress a blood
2 vessel.
- 1 141. The method of claim 140 wherein the blood vessel is an artery feeding a tumor.
- 1 142. A method of delivering a fastener into a herniated or bulging intervertebral disc, the
2 method comprising the steps of:
3 a) compressing a bulge or herniation of the intervertebral disc;
4 b) and deploying a fastener into the intervertebral disc to hold the herniation or bulge in
5 a compressed position.

- 1 143. The method of claim 142 wherein said fastener resiliently holds the herniation or bulge in
2 the compressed position.
- 1 144. The method of claim 142 wherein said fastener device is a screw and said screw is
2 rotatably inserted into the intervertebral disc.
- 1 145. The method of claim 144 wherein a washer is attached on an end of said screw.
- 1 146. The method of claim 144 wherein said screw has a variable pitch thread, thereby
2 allowing the user to compress the intervertebral disc as the screw is rotated into the
3 intervertebral disc.
- 1 147. The method of claim 144 wherein said screw has a locking device to lock said screw in
2 place within the intervertebral disc.
- 1 148. The method of claim 142 wherein said fastener device comprises a suture used to tie and
2 compress the bulge in the intervertebral disc.
- 1 149. The method of claim 148 wherein said suture is formed of metal.
- 1 150. The method of claim 148 wherein said suture has an anchoring device.
- 1 151. The method of 148 wherein a washer is tied to the intervertebral disc by said suture.
- 1 152. The method of claim 142 wherein said fastener is a tack which is pressed into the bulge.
- 1 153. The method of claim 142 wherein said fastener is a staple which is pressed into the
2 bulge.
- 1 154. The method of claim 142 wherein said fastener is a clamp which is positioned around the
2 bulge.
- 1 155. The method of claim 142 wherein said fastener is a tissue anchor used to press the
2 bulging tissue against the intervertebral disc.

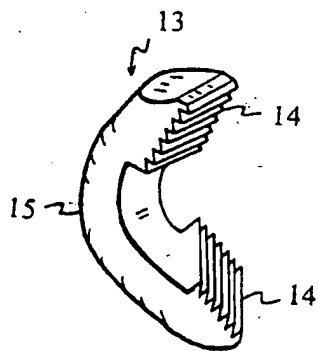


Figure 1

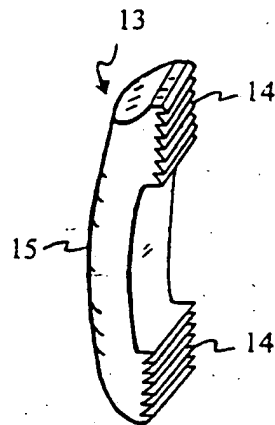


Figure 2

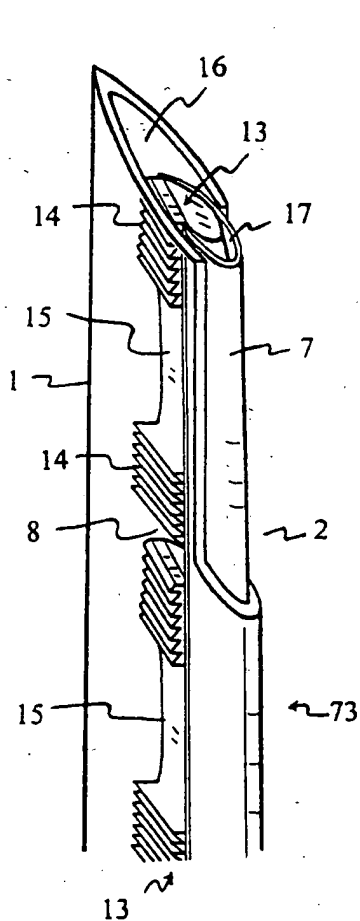


Figure 3

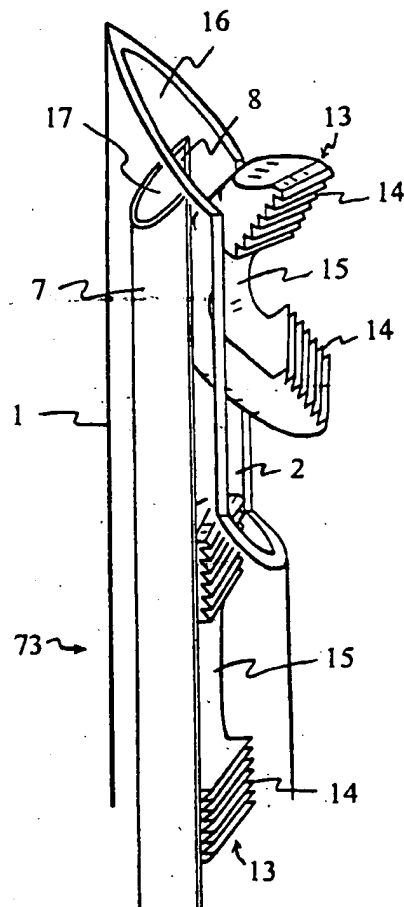


Figure 4

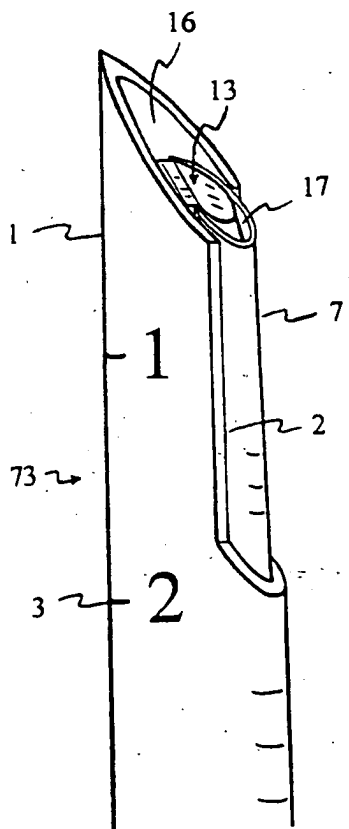


Figure 5

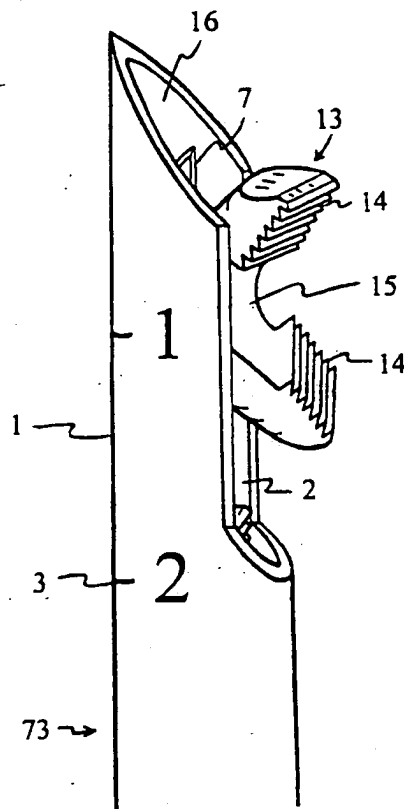


Figure 6

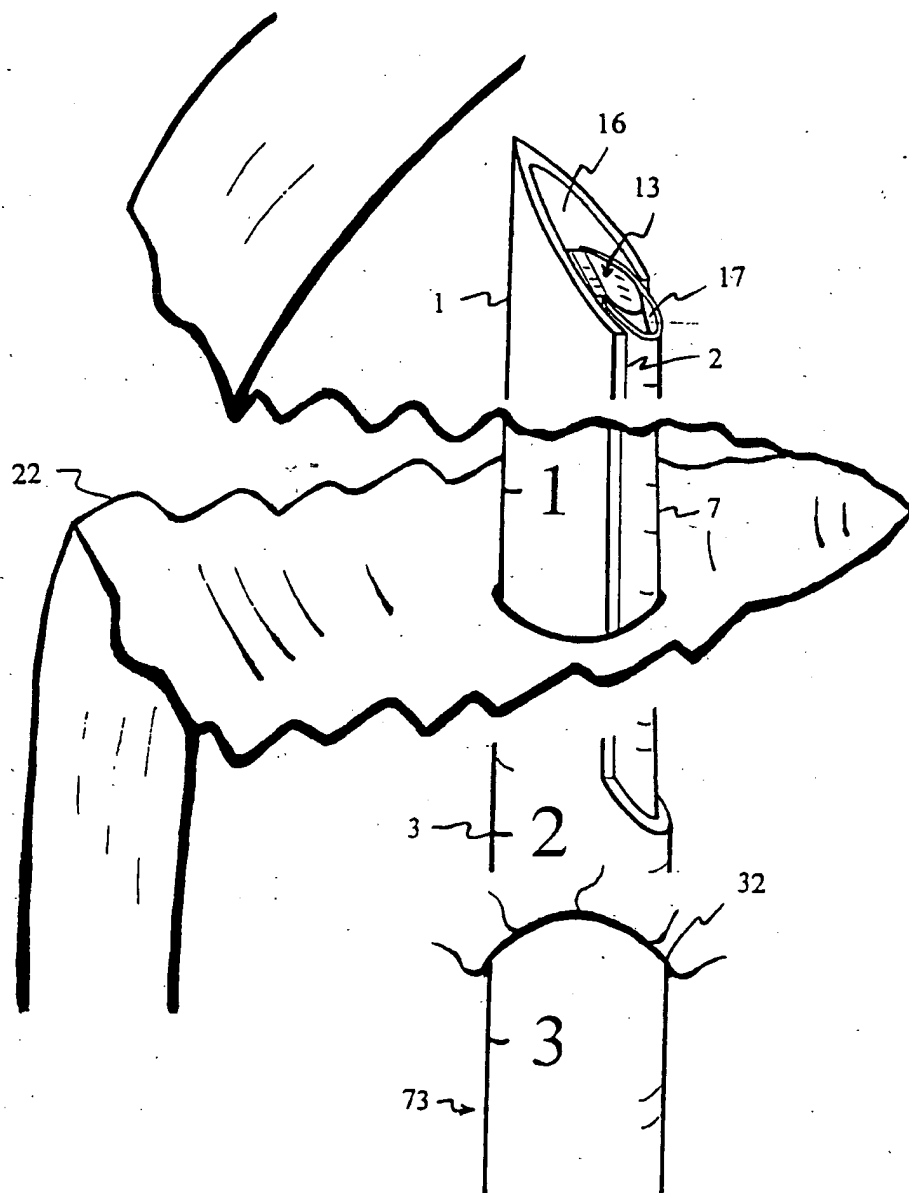


Figure 7

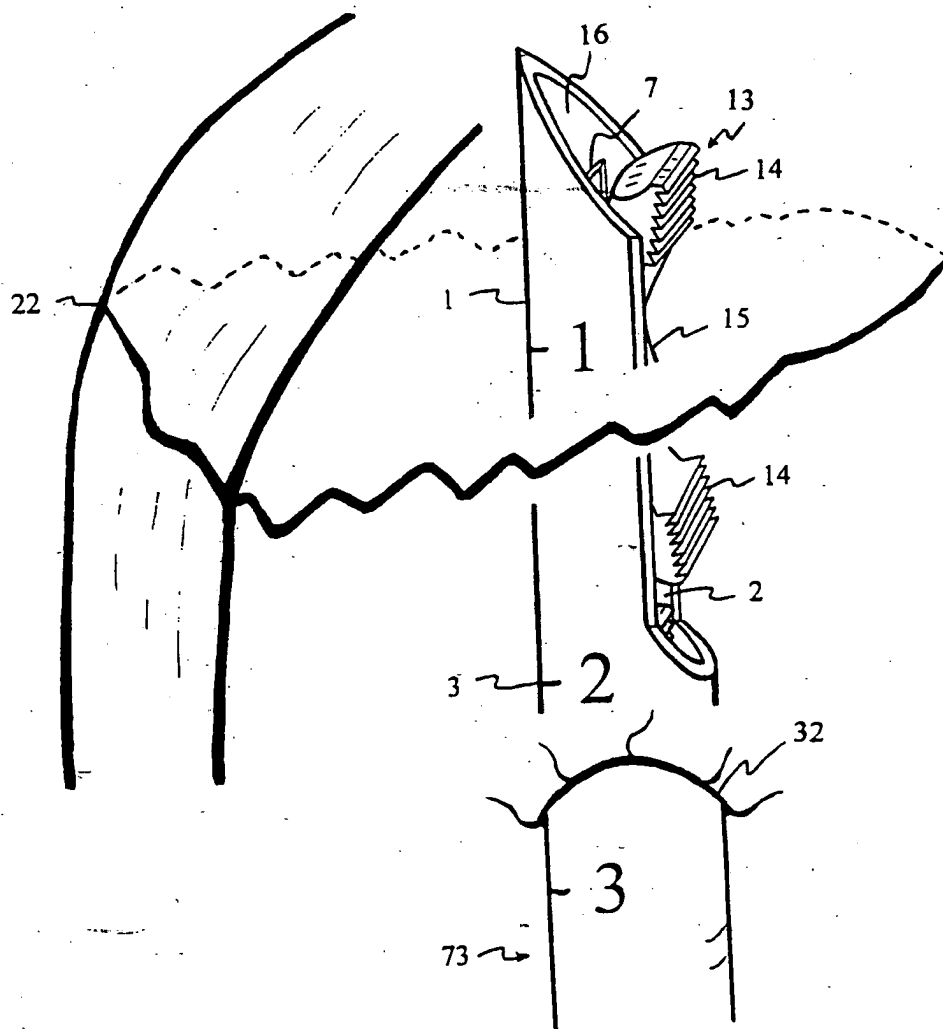


Figure 8

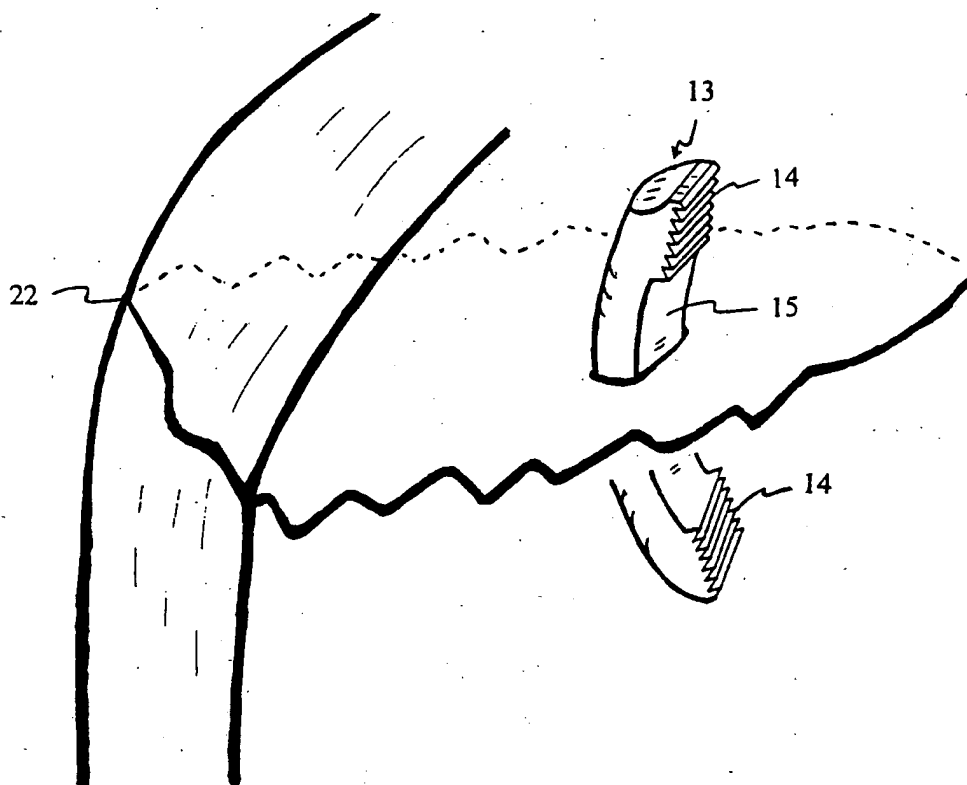


Figure 9

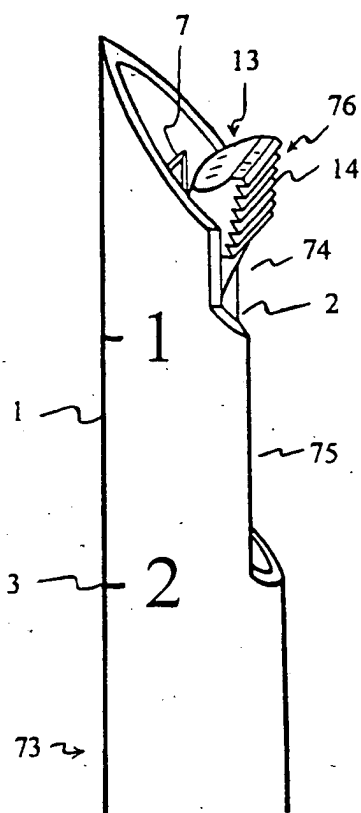


Figure 10

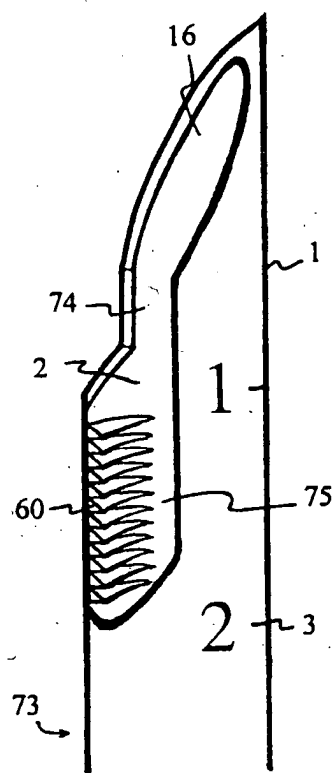


Figure 11

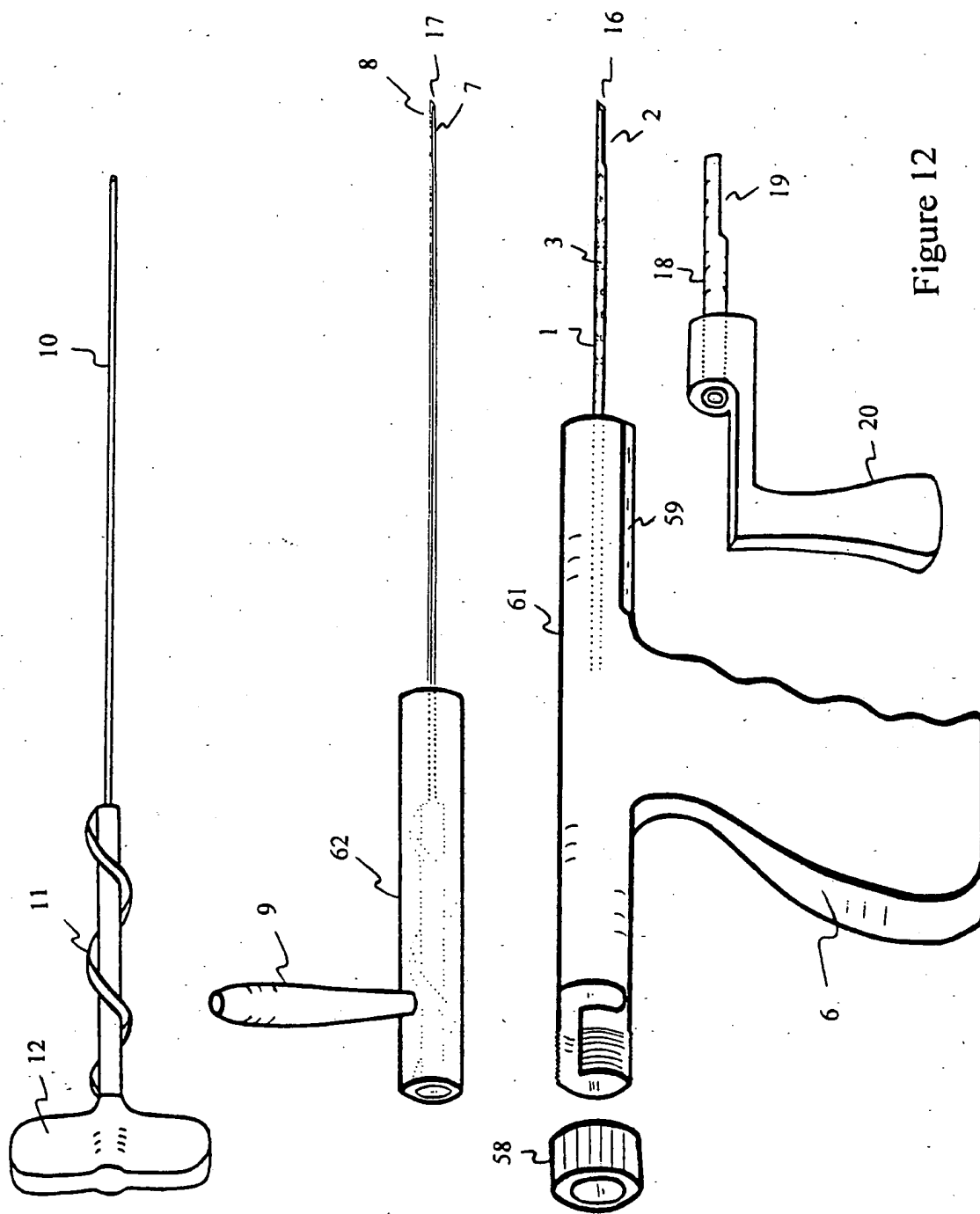


Figure 12

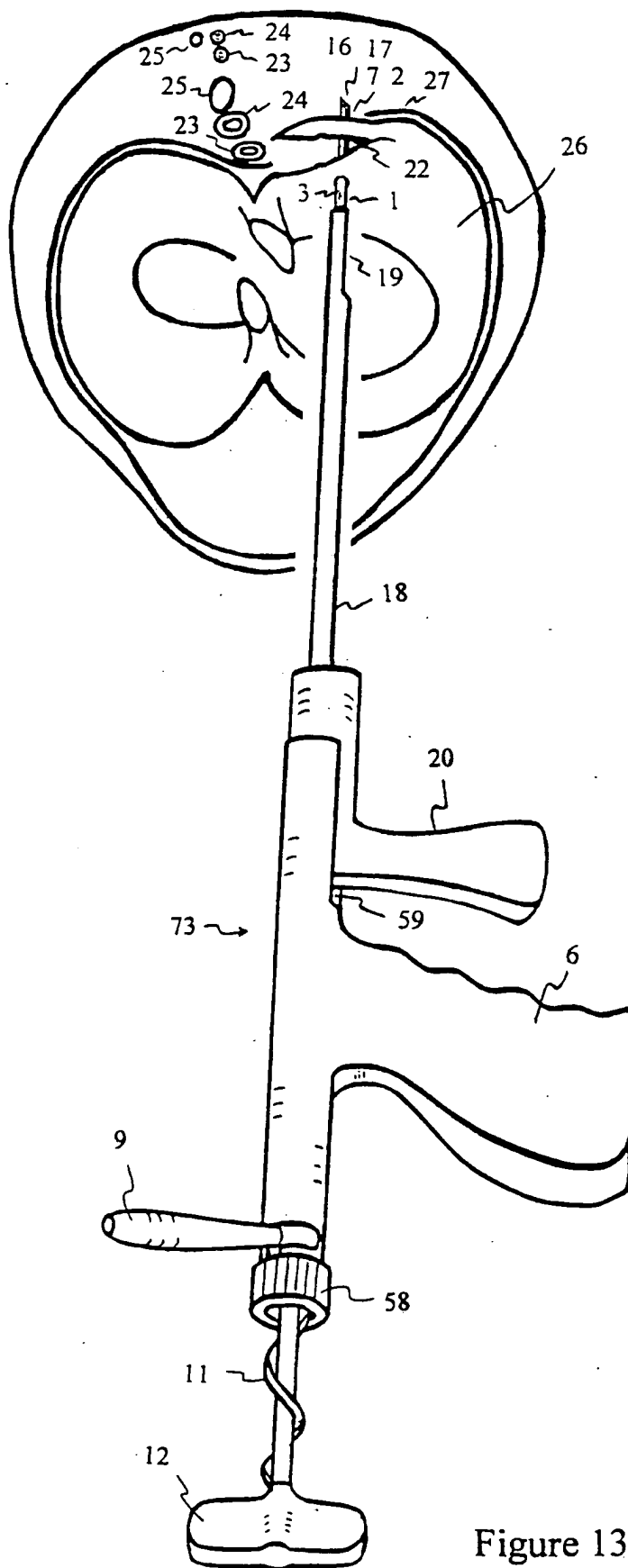


Figure 13

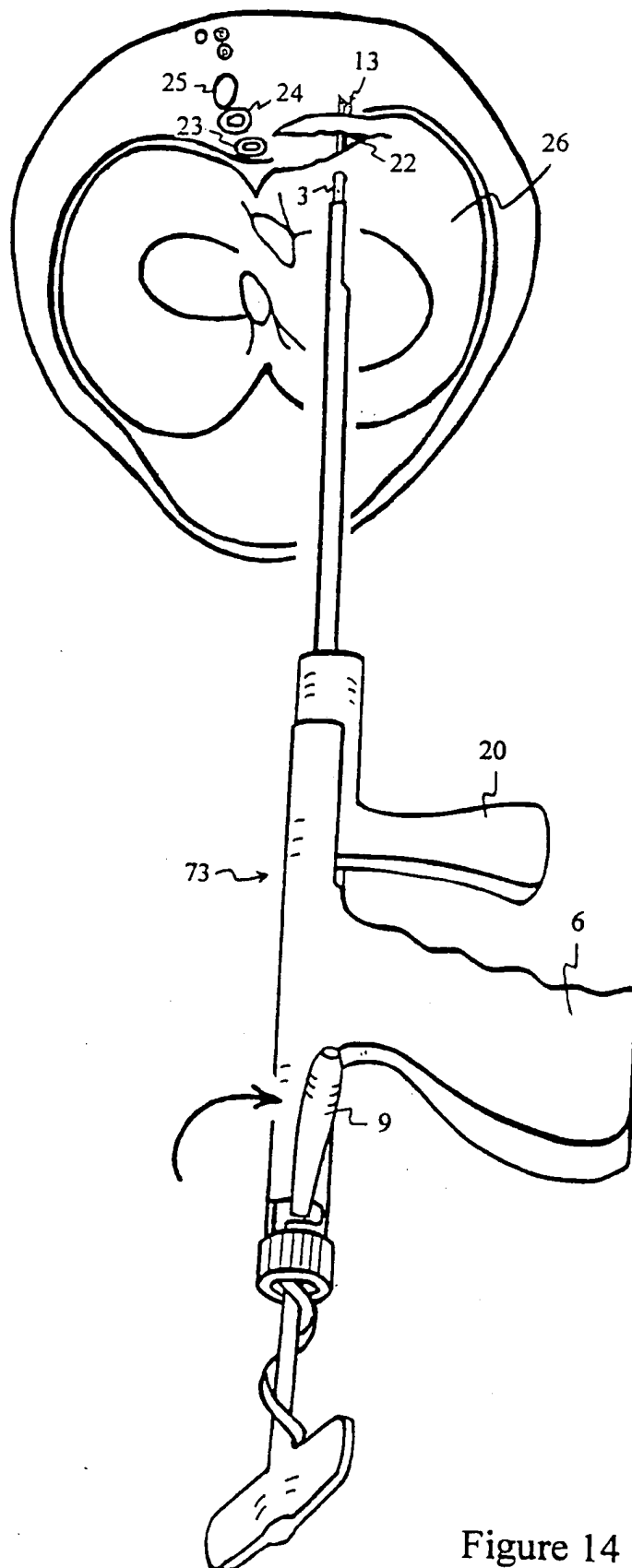


Figure 14

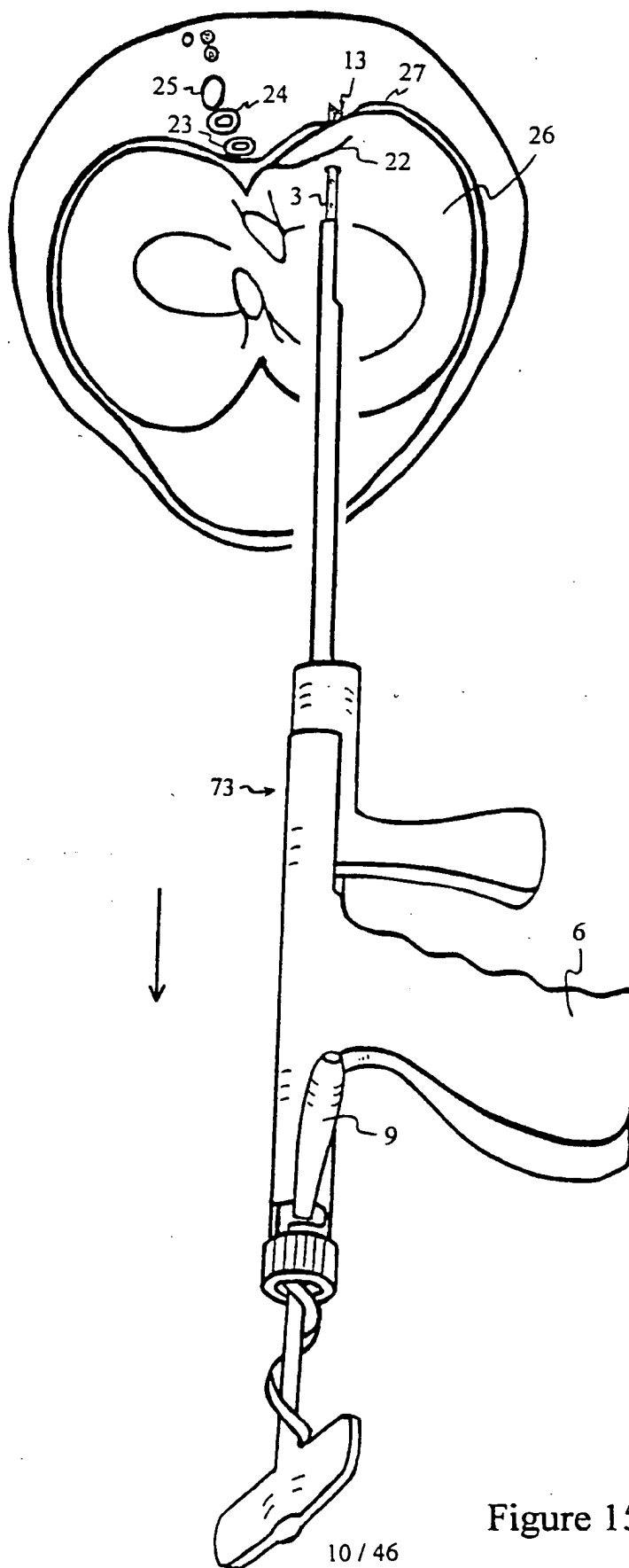


Figure 15

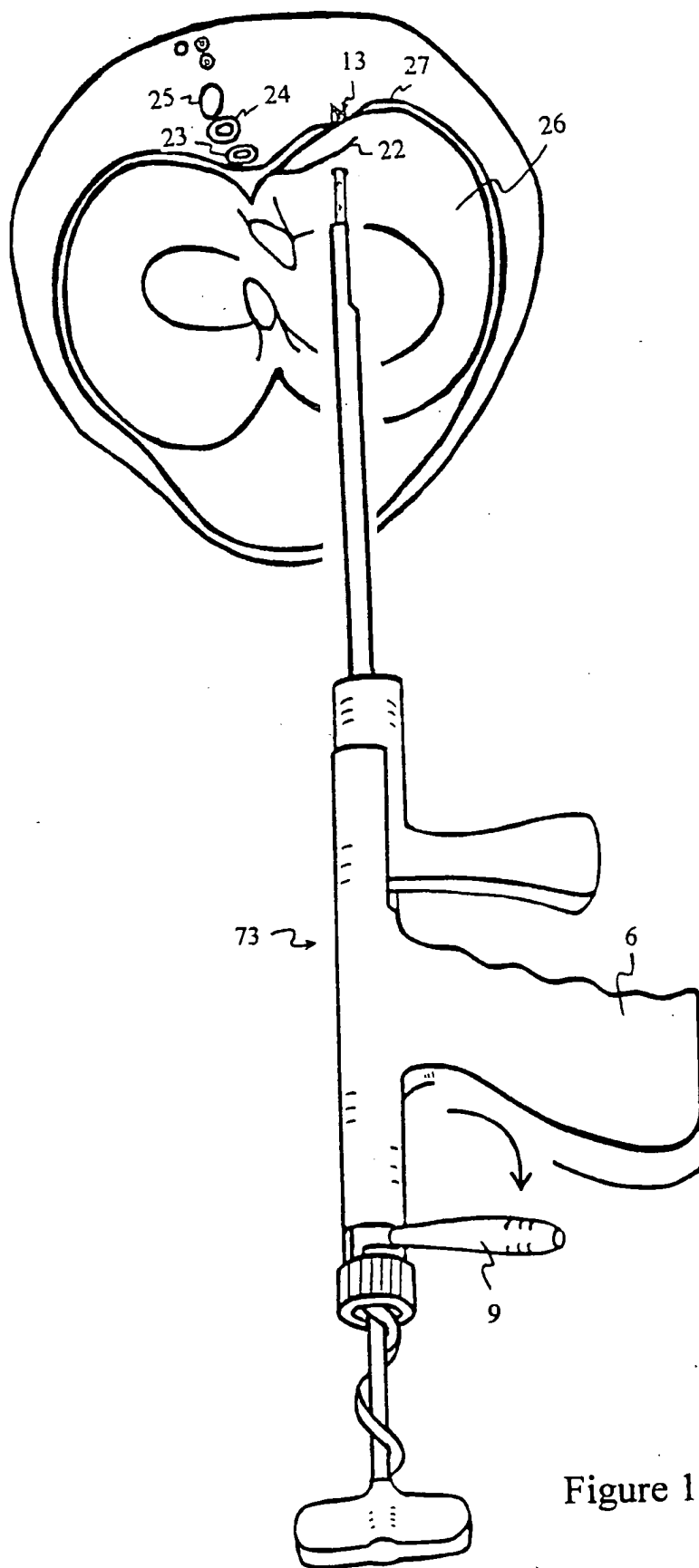


Figure 16

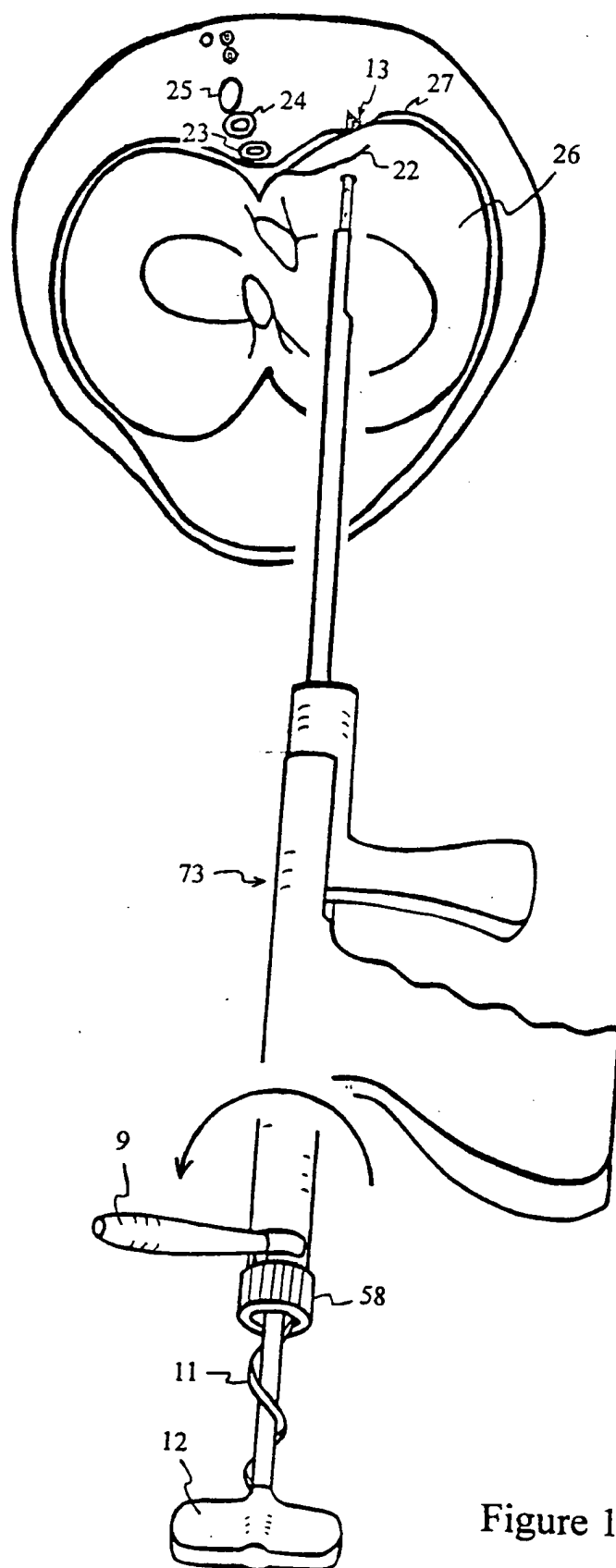


Figure 17

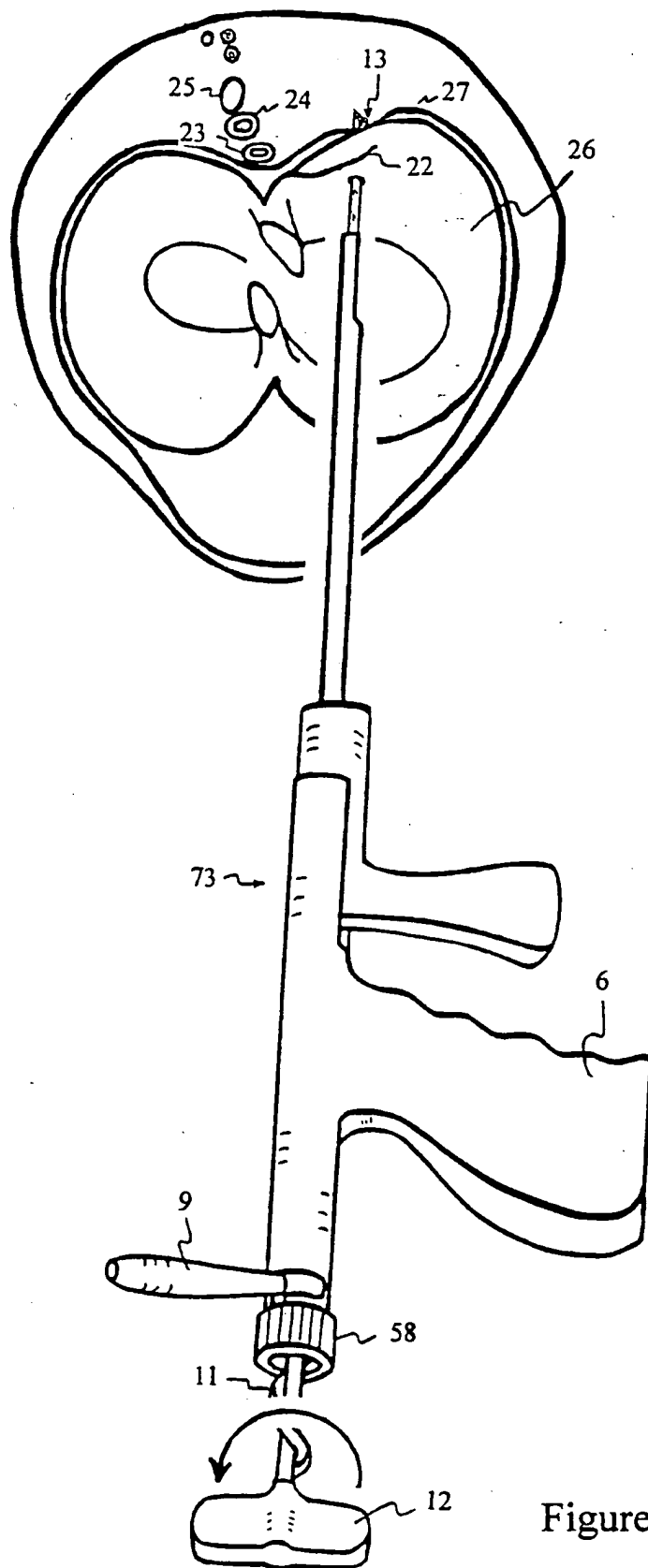


Figure 18

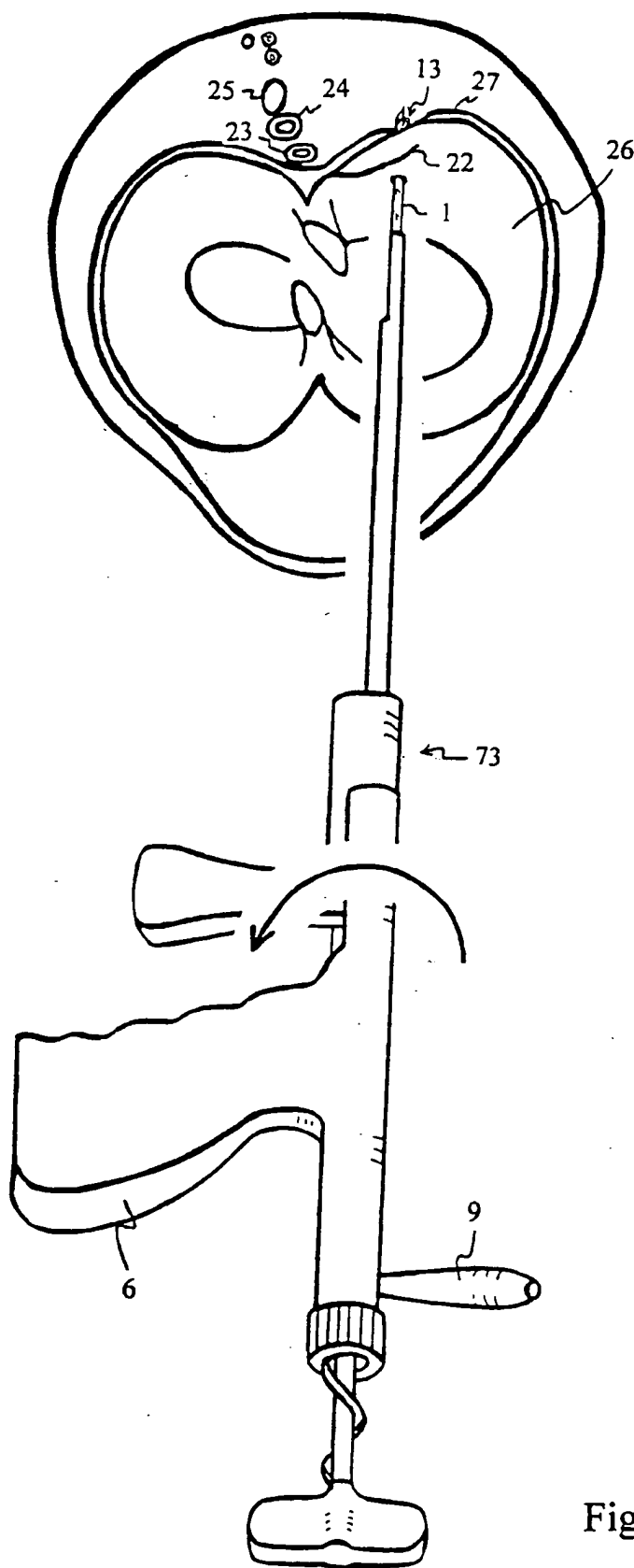


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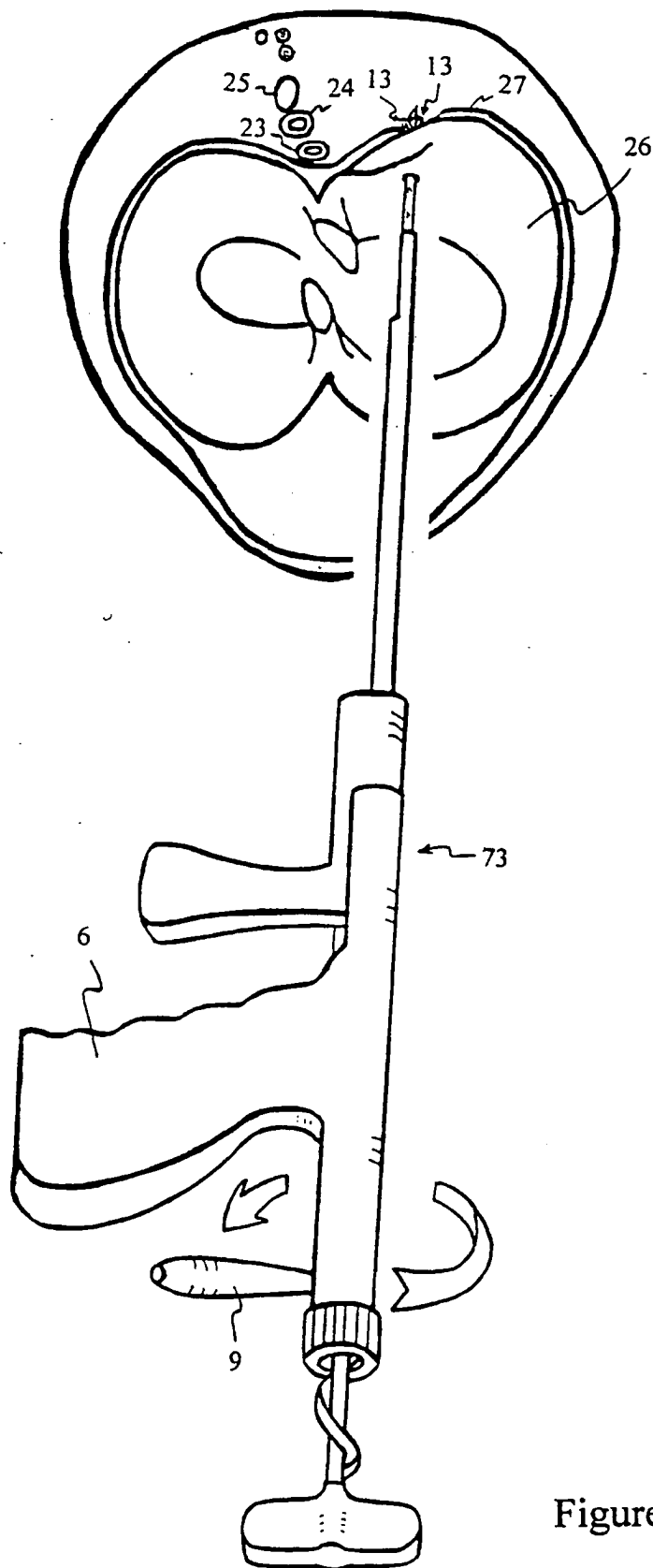


Figure 20

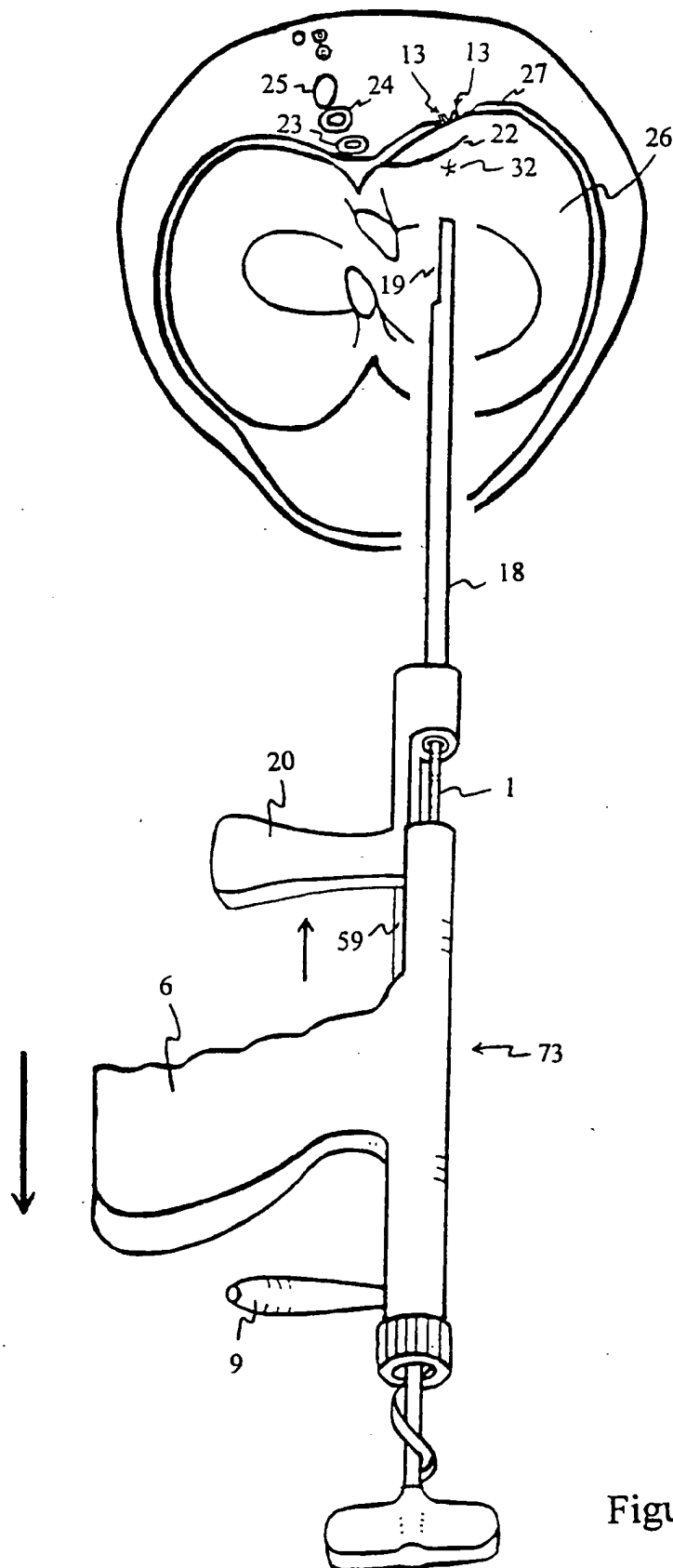


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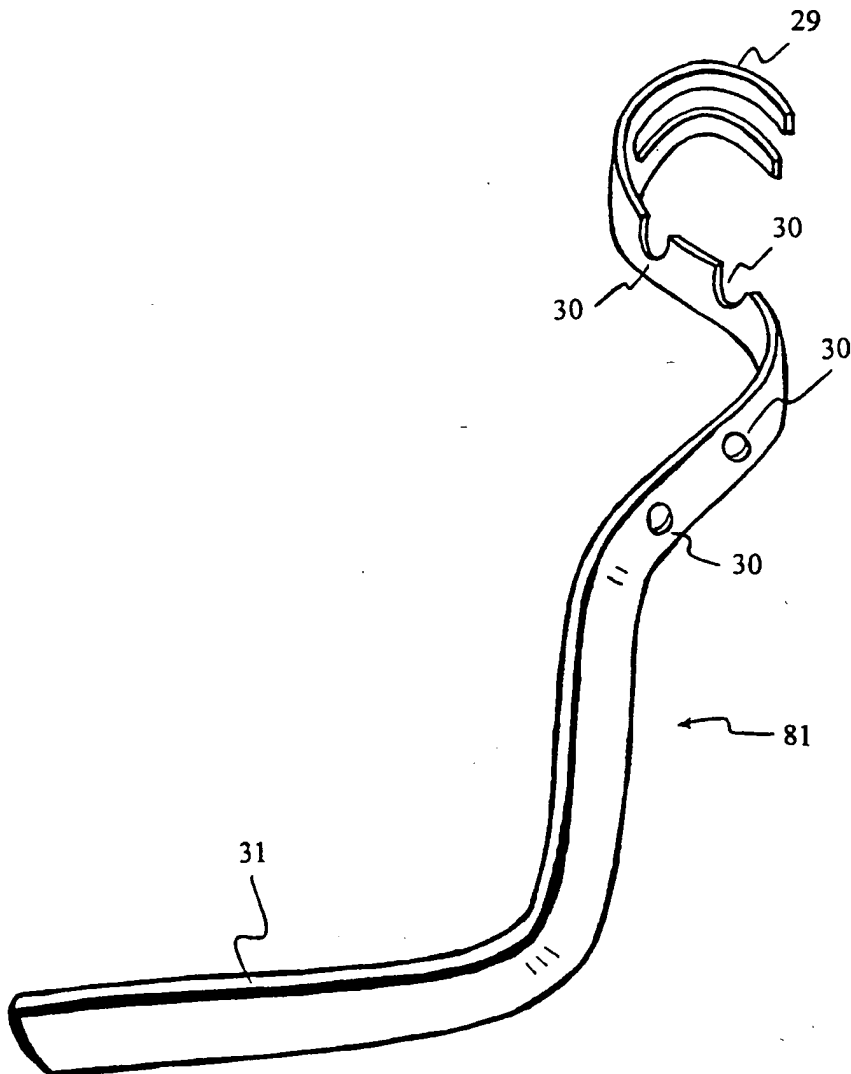


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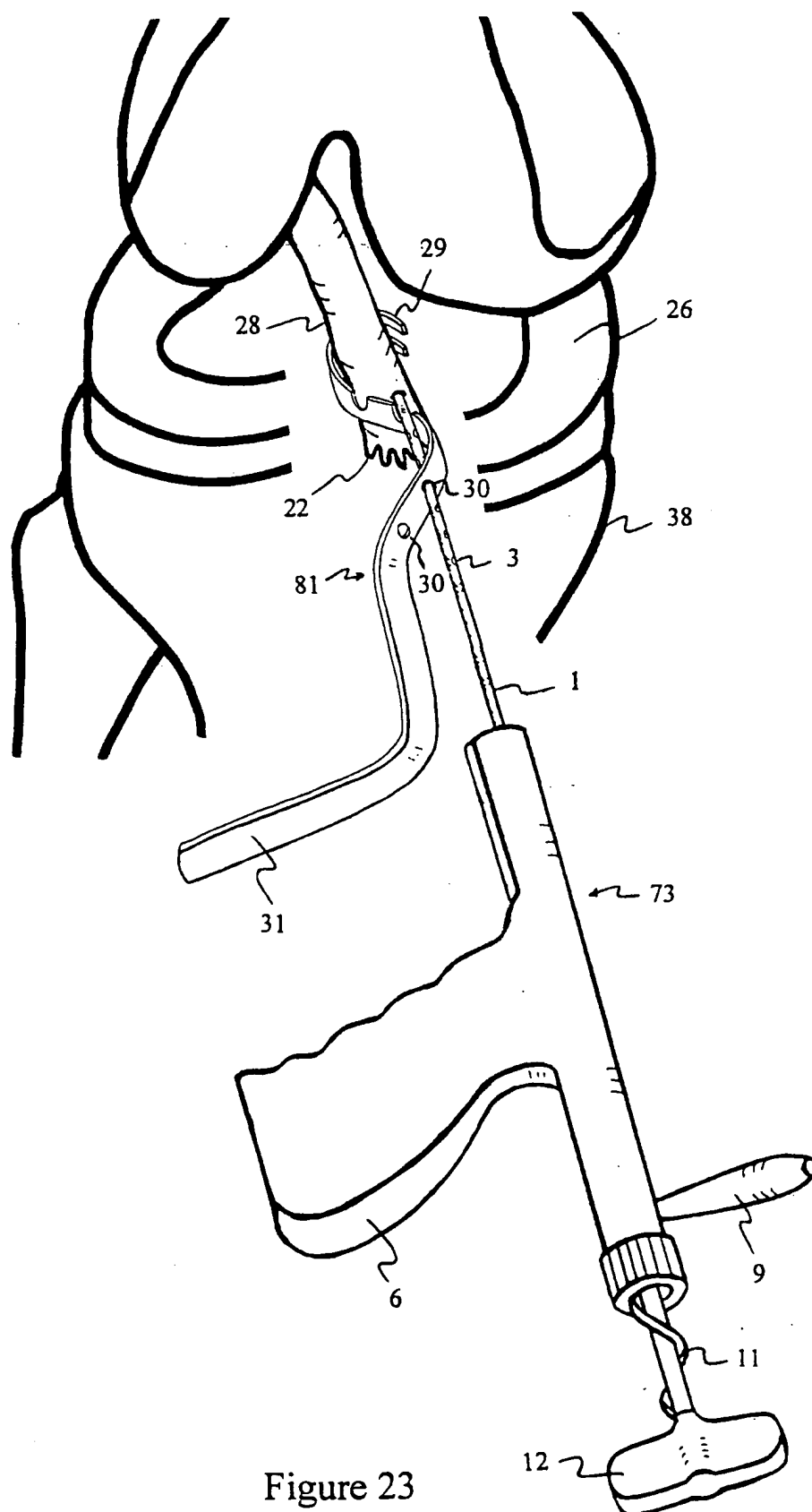


Figure 23

Figure 24

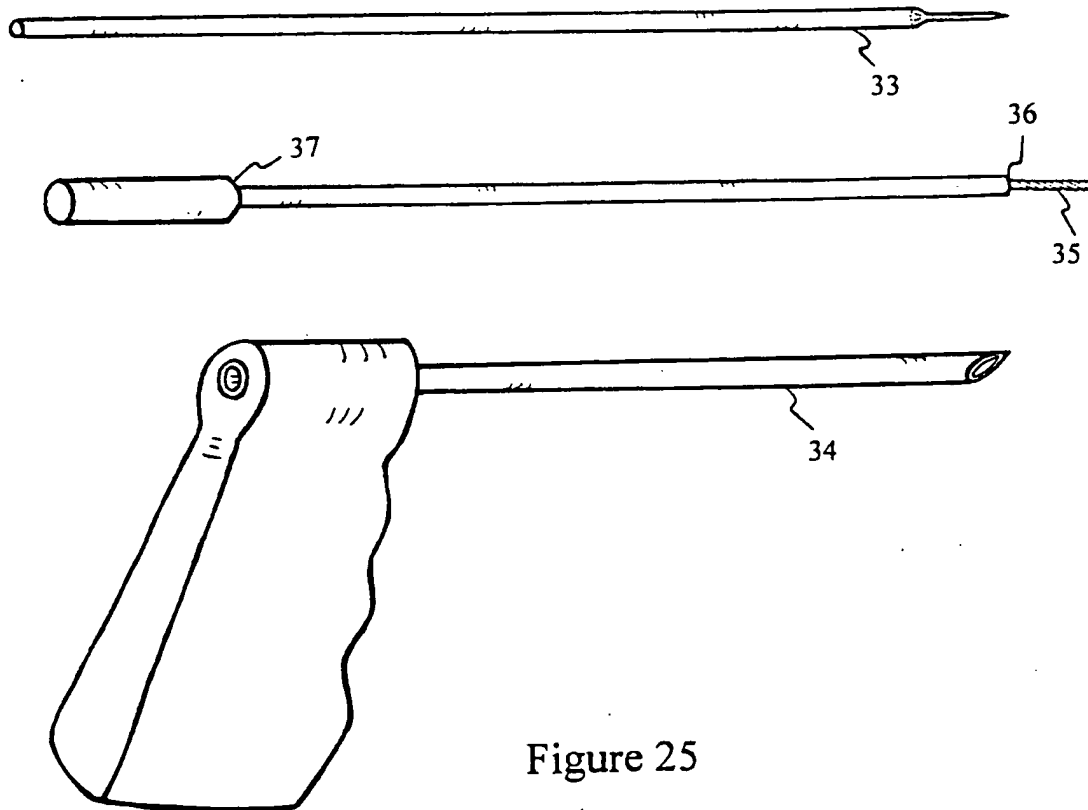
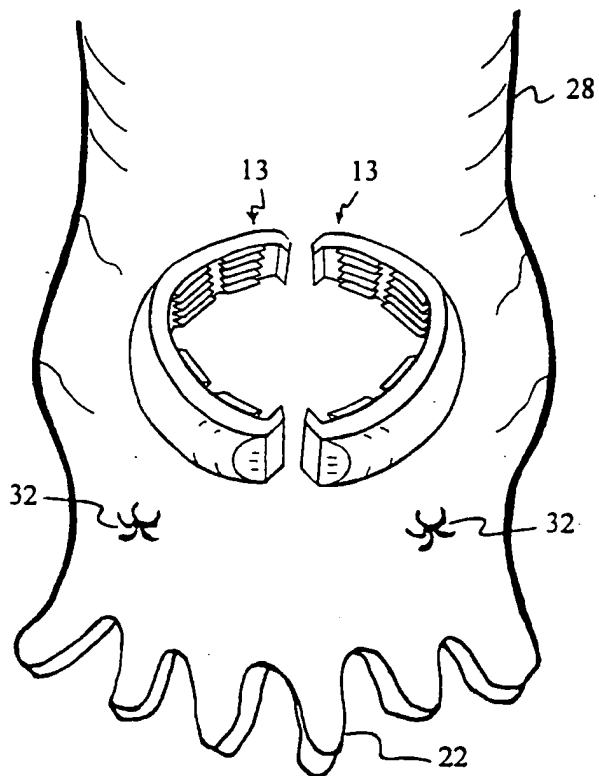


Figure 25

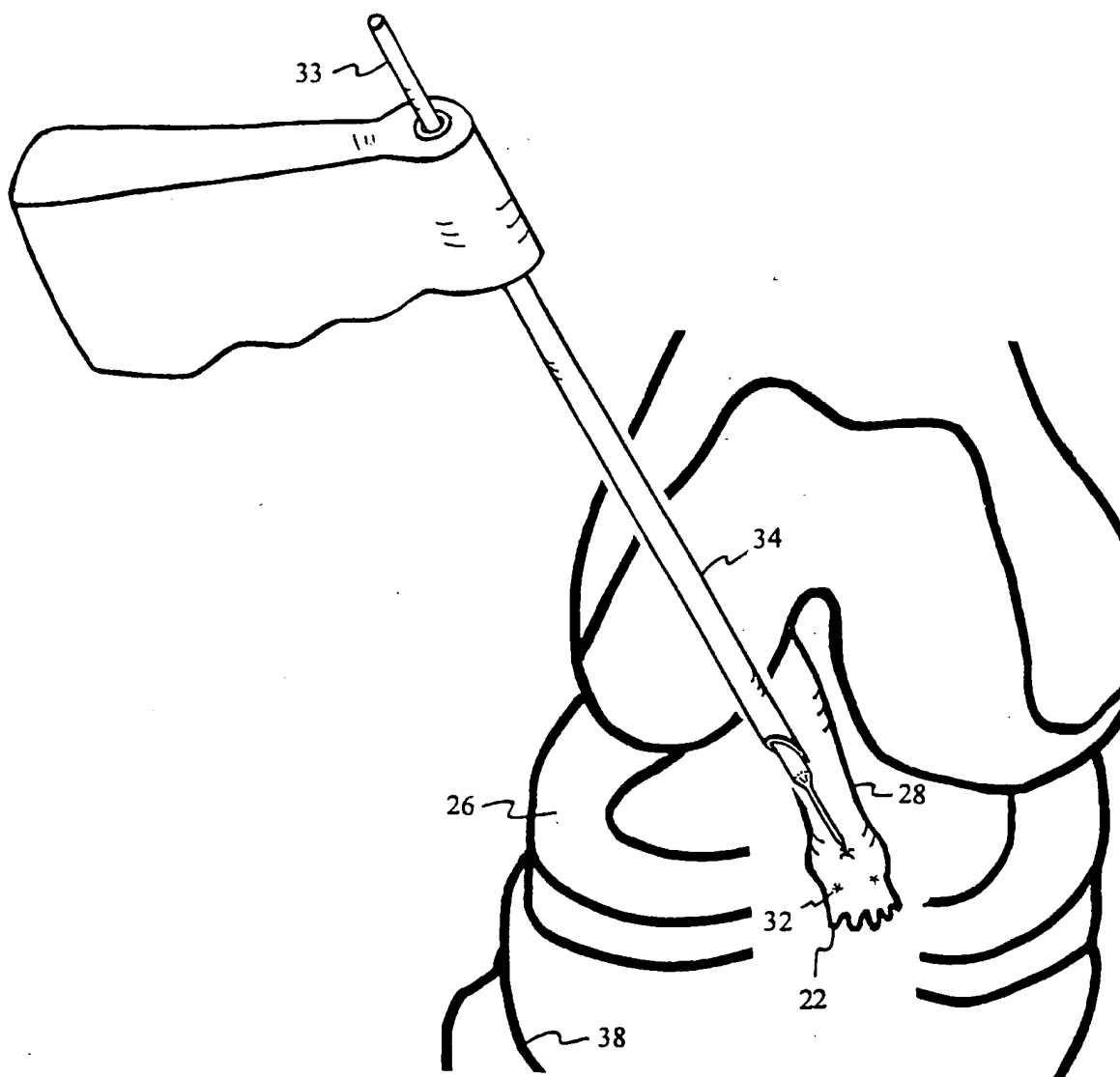


Figure 26

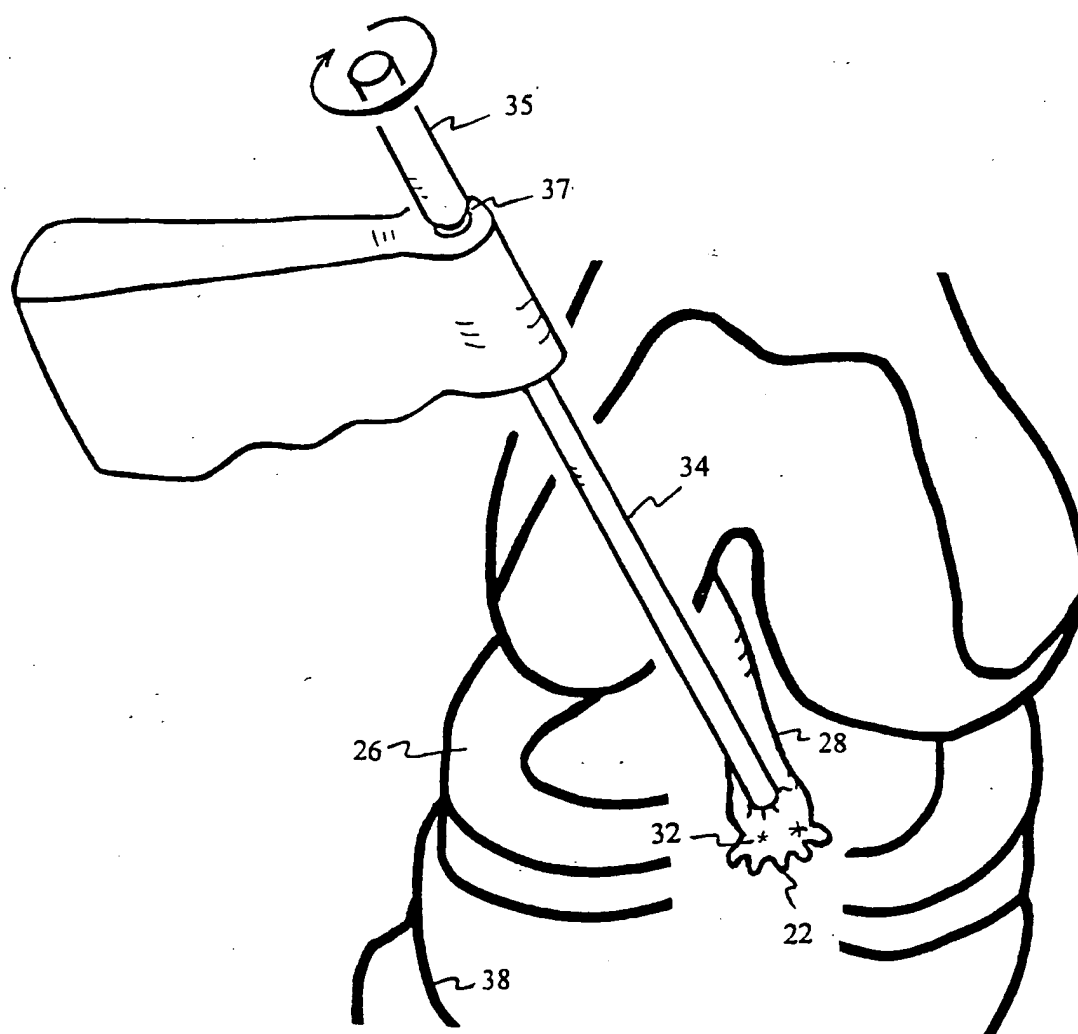


Figure 27

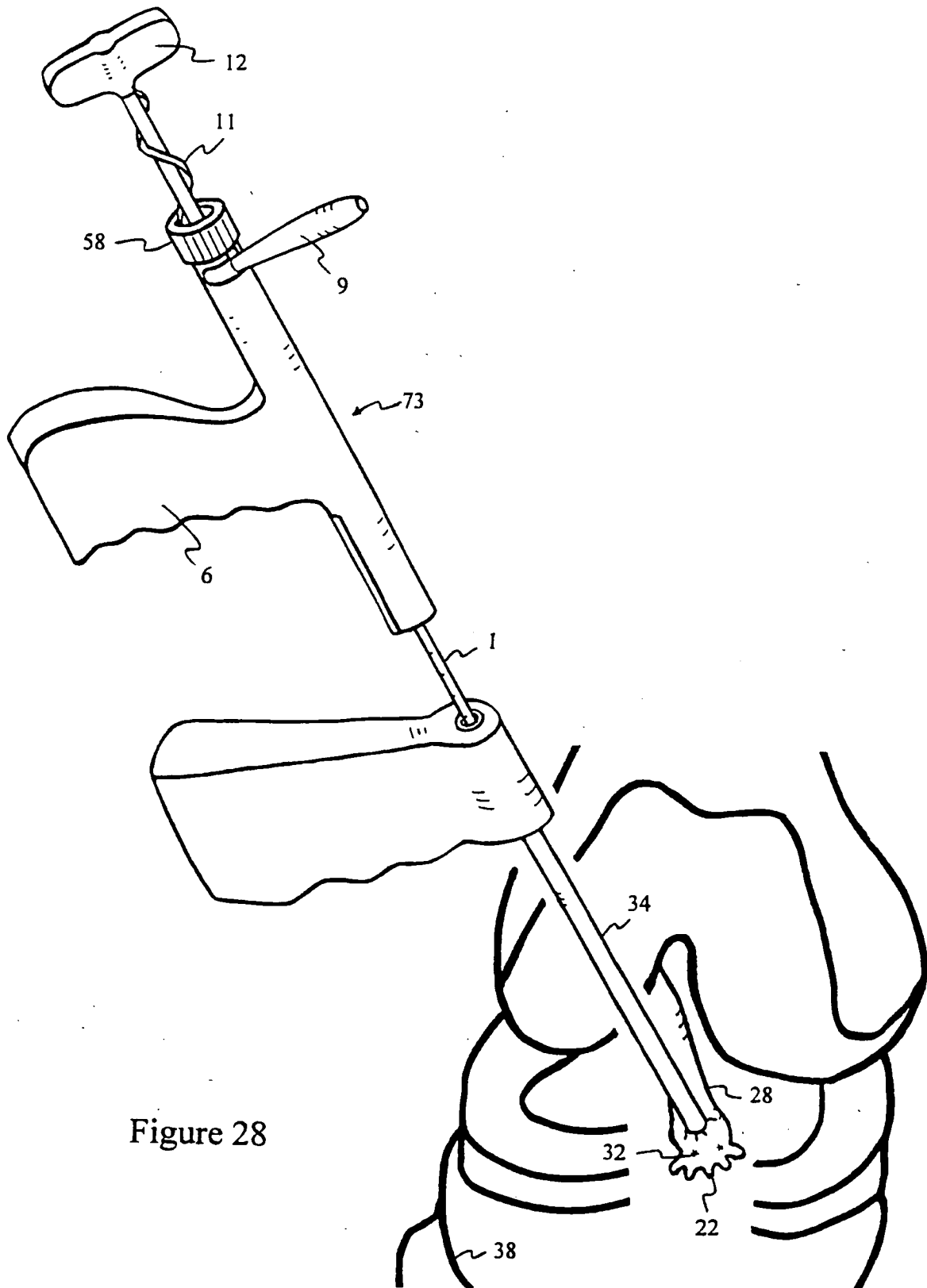


Figure 28

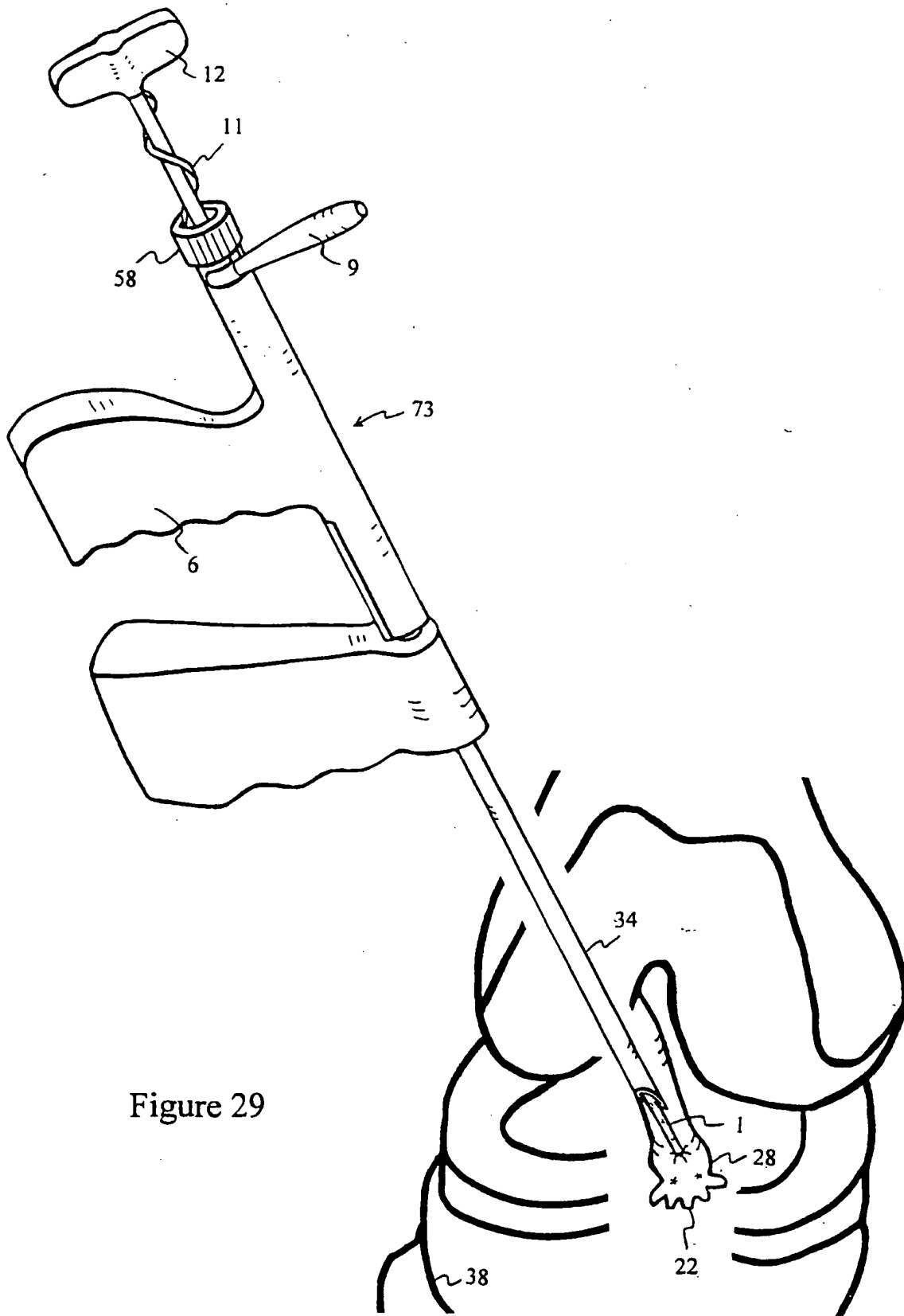


Figure 29

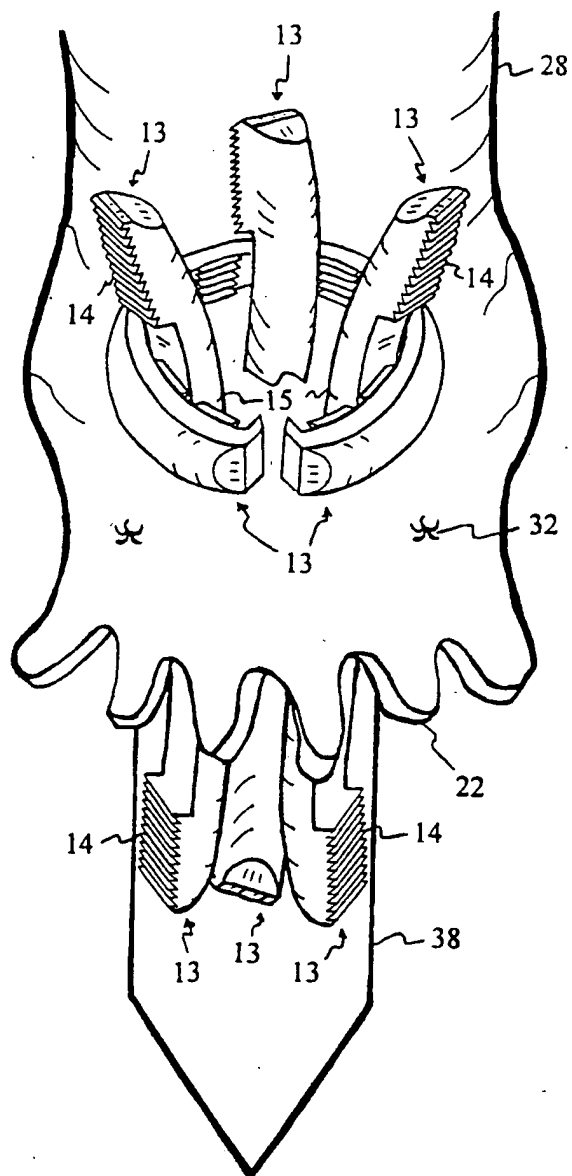


Figure 30

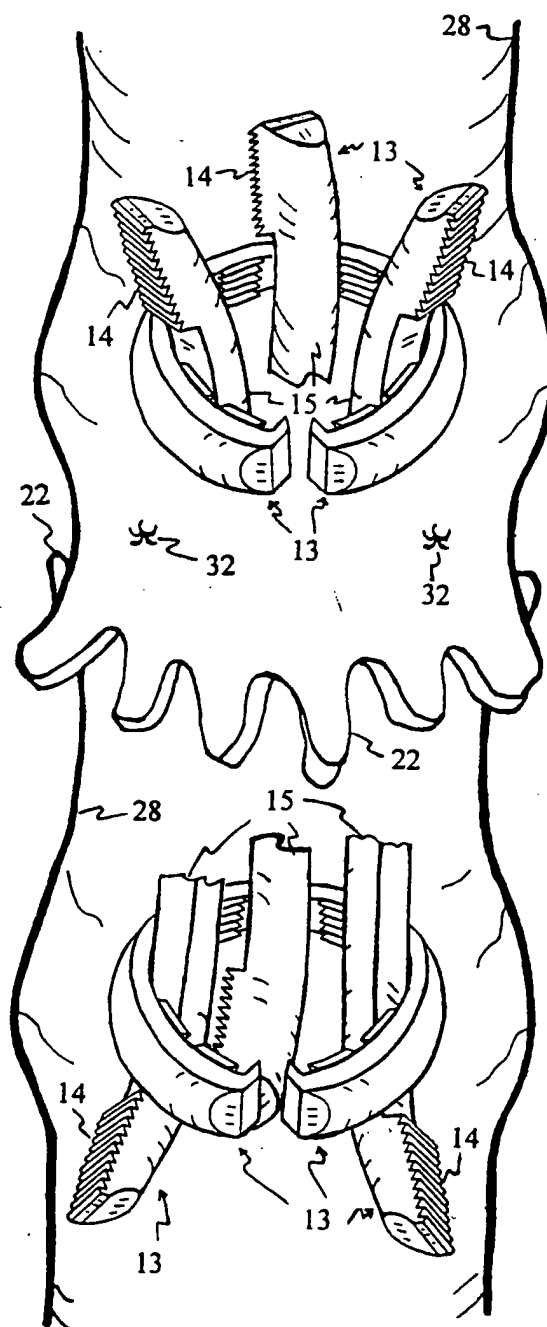


Figure 31

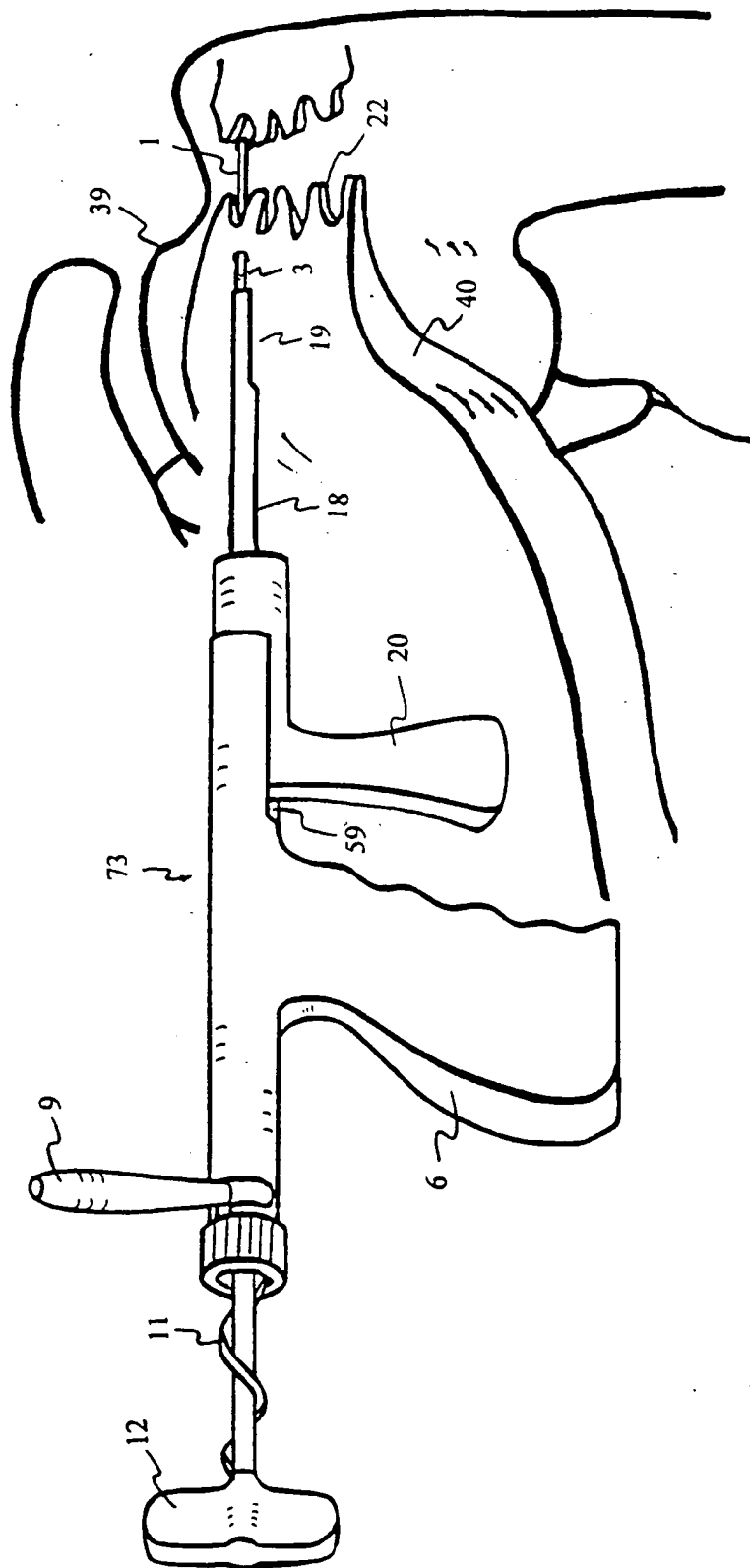


Figure 32

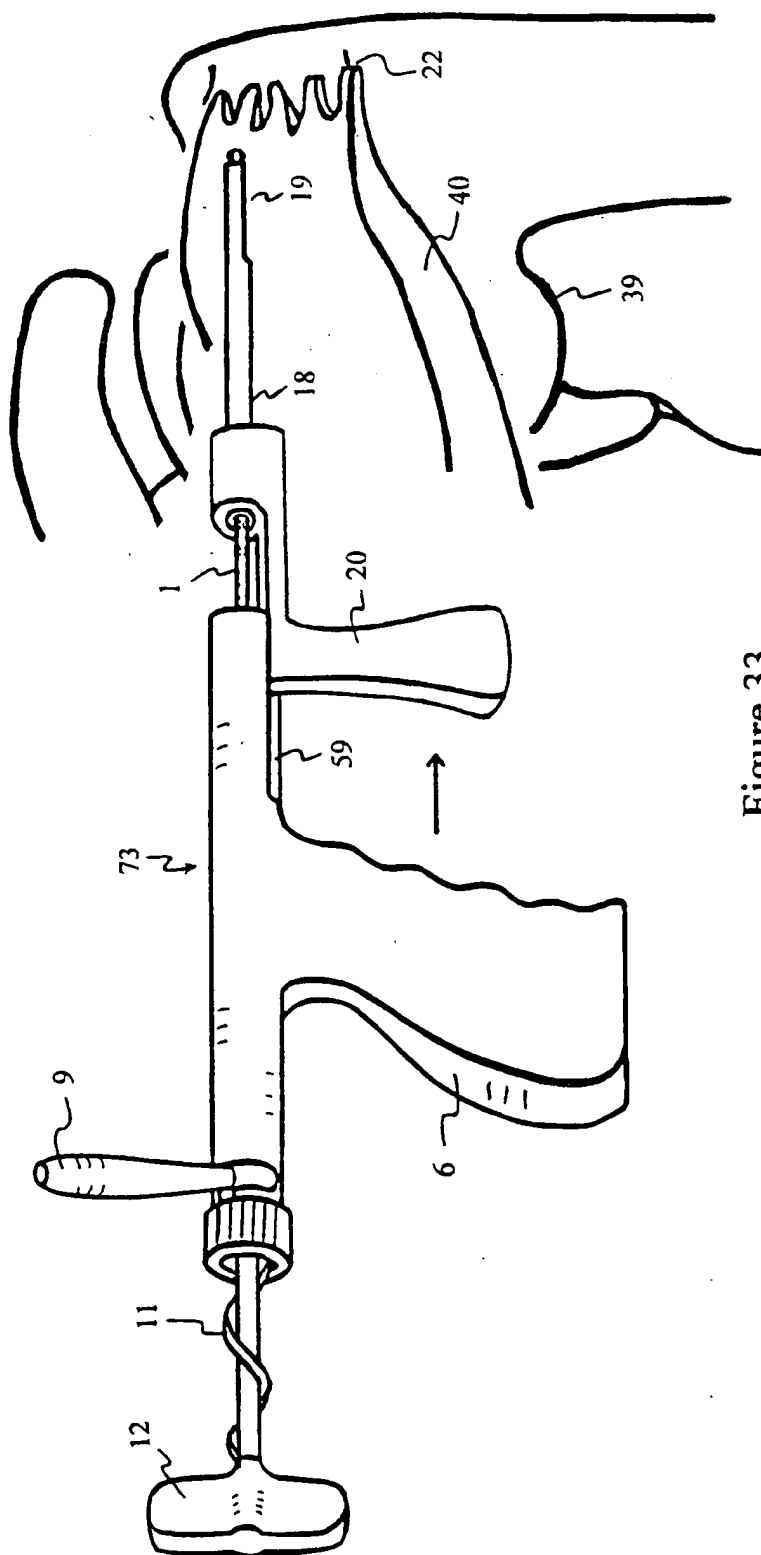


Figure 33

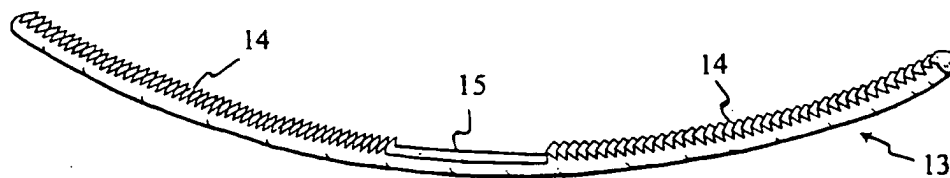


Figure 34

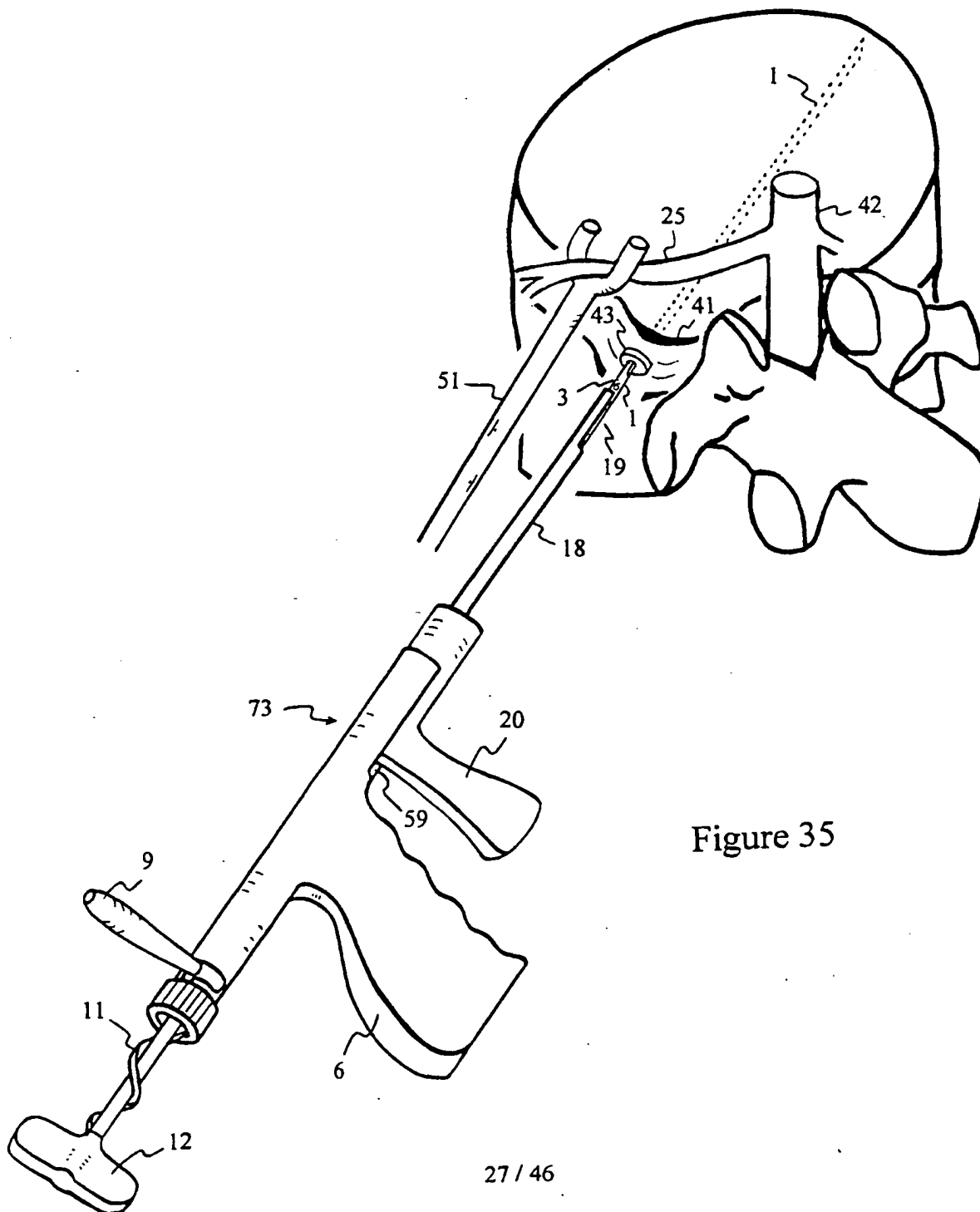


Figure 35

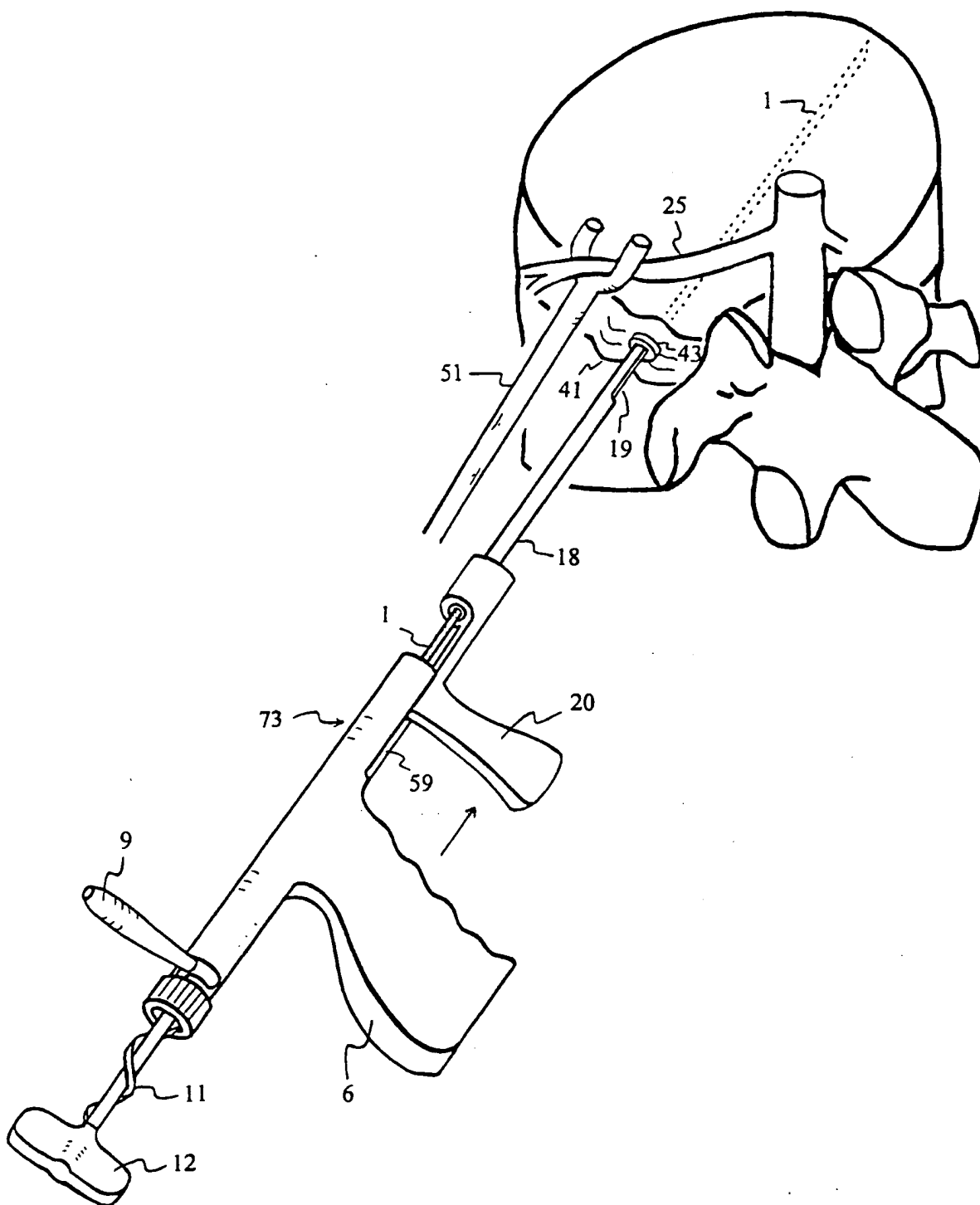


Figure 36

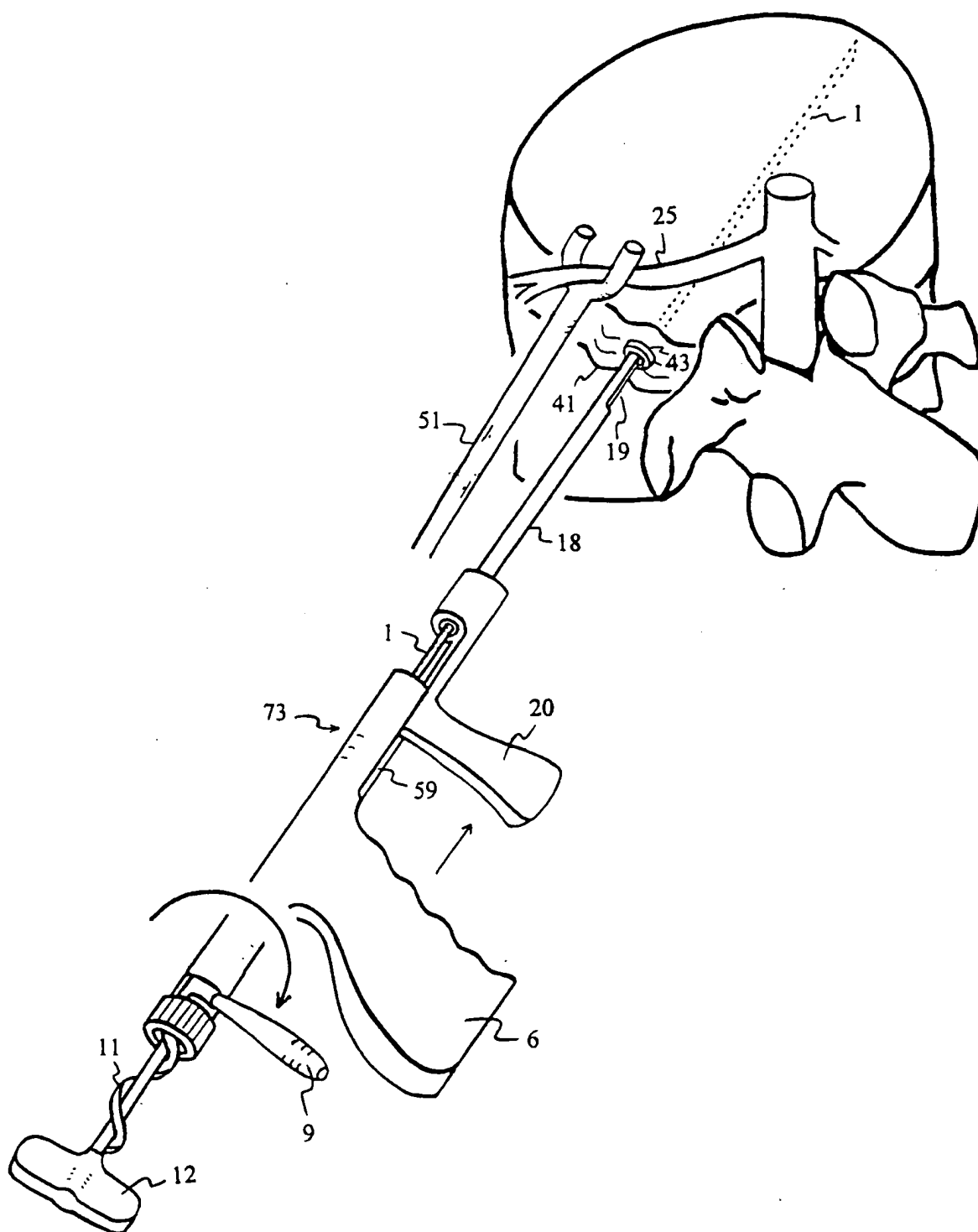


Figure 37

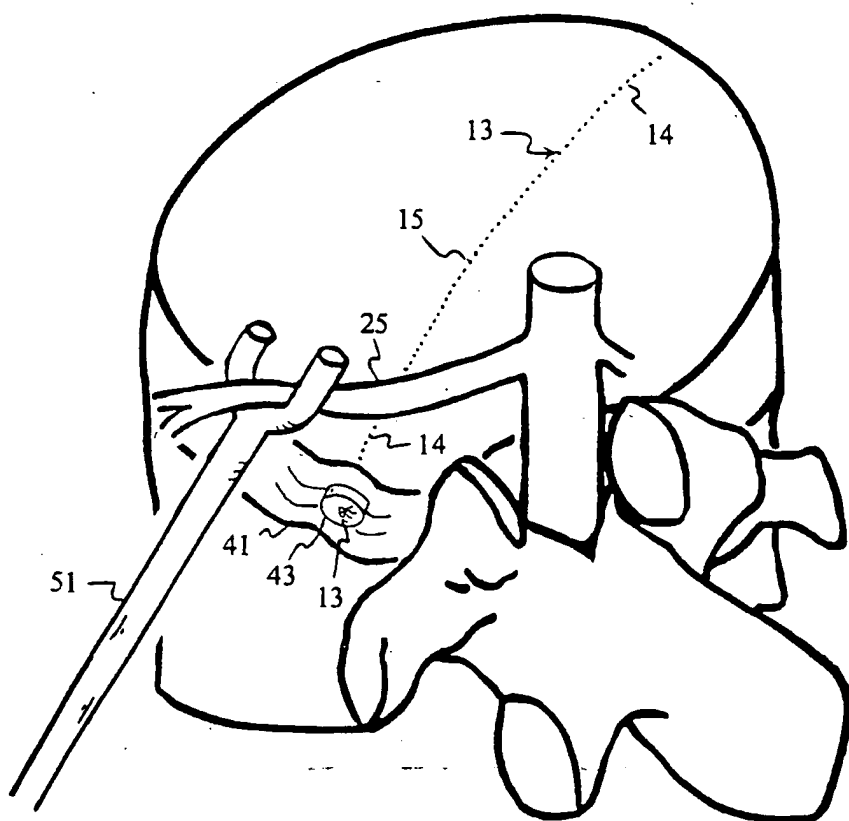


Figure 38

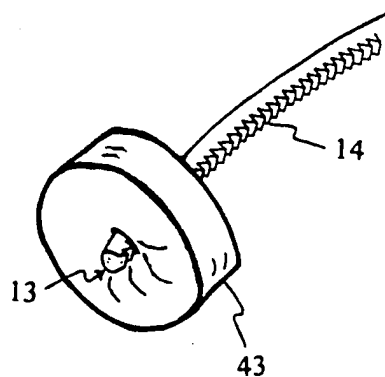


Figure 39

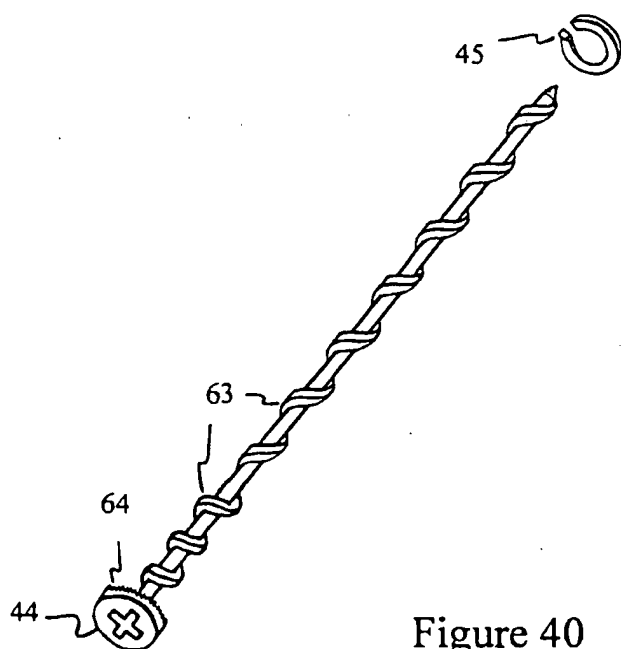


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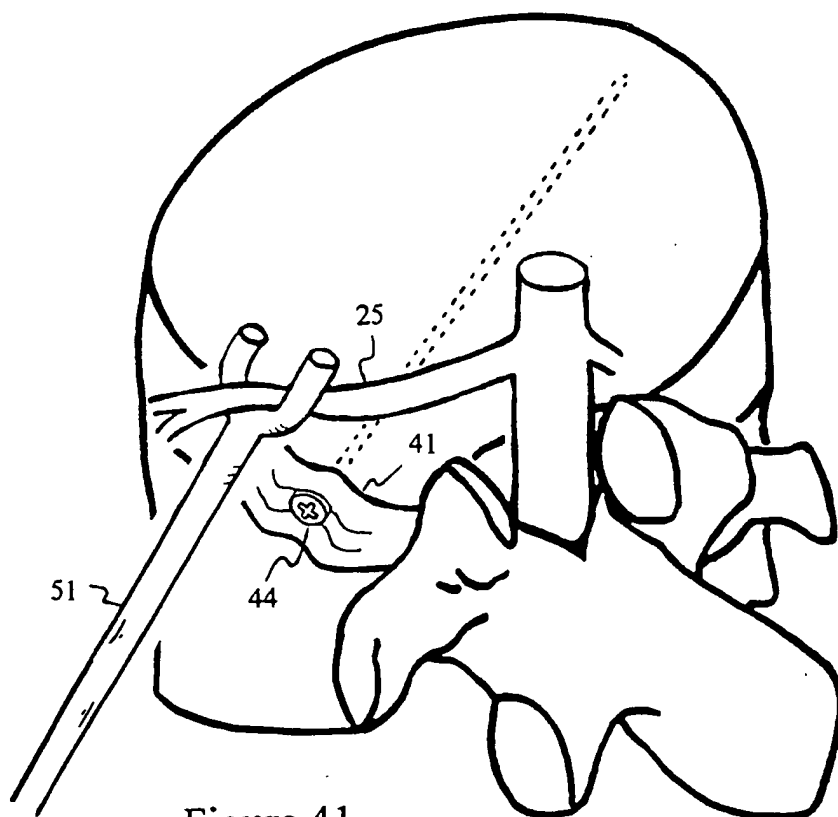
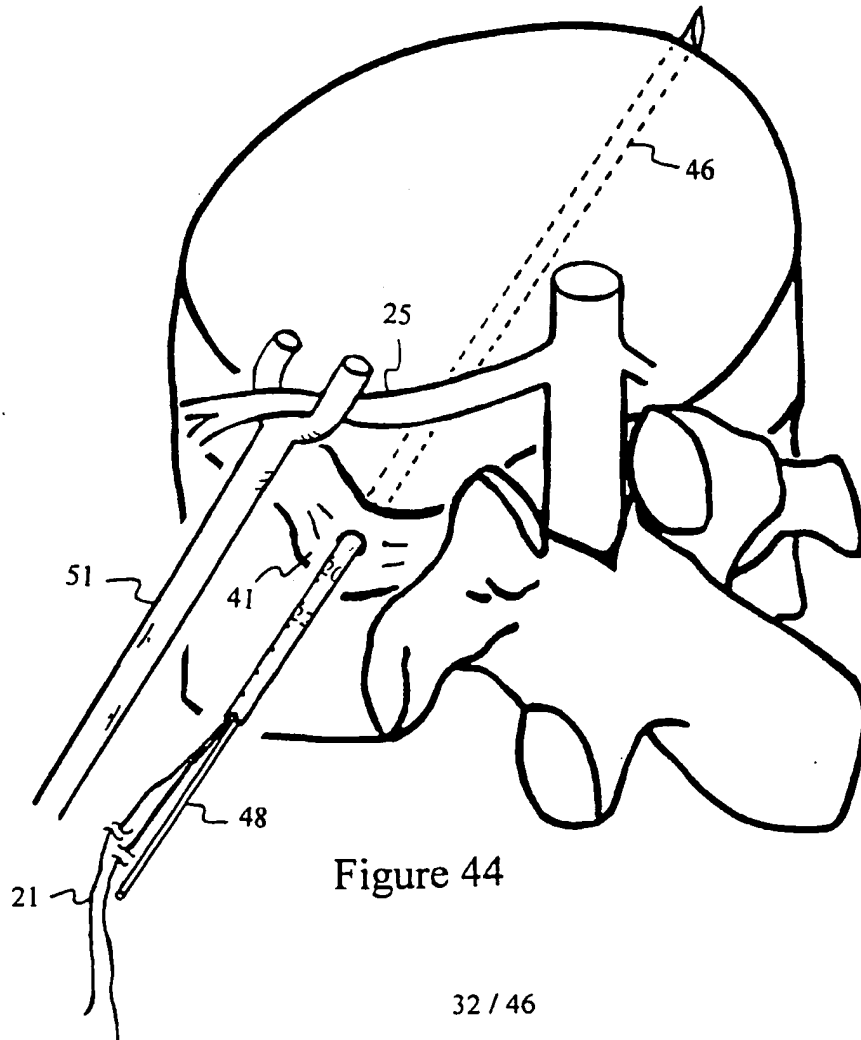
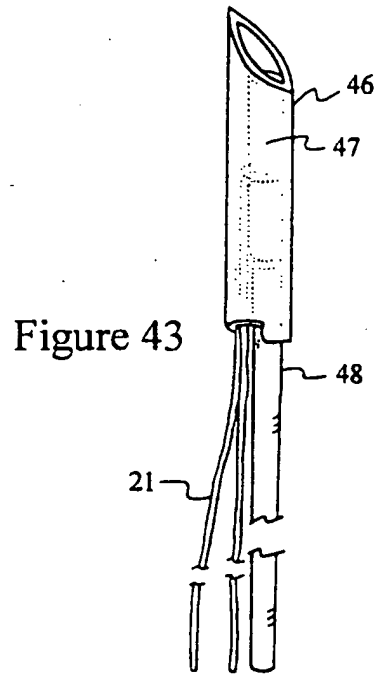
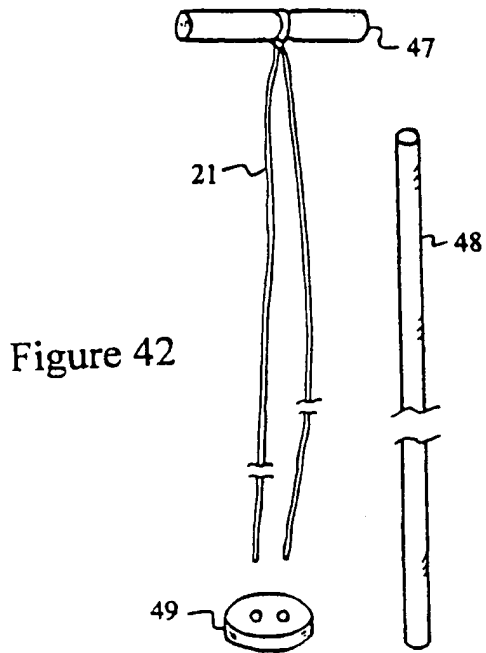
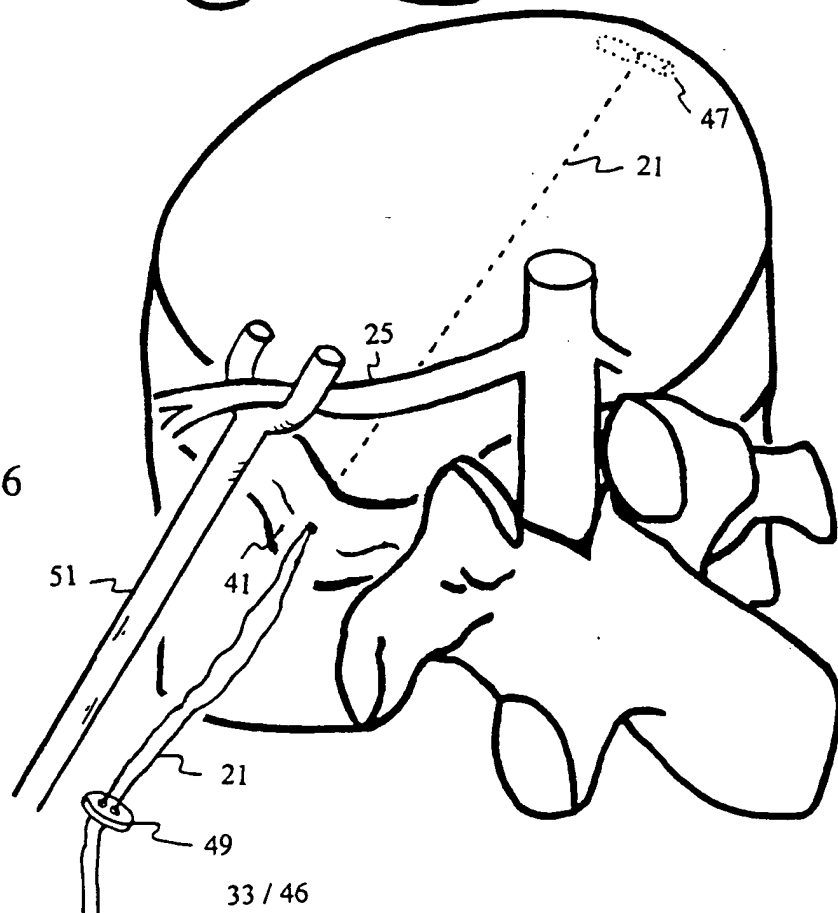
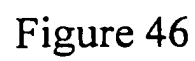
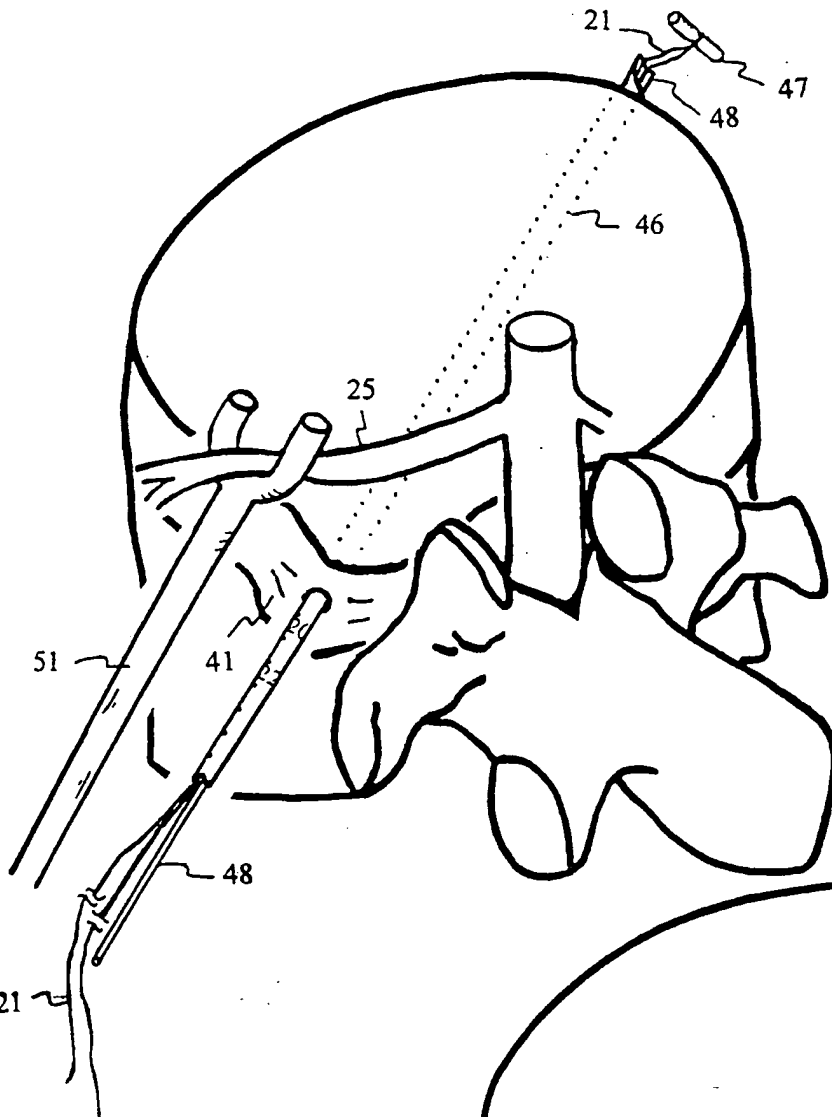


Figure 41





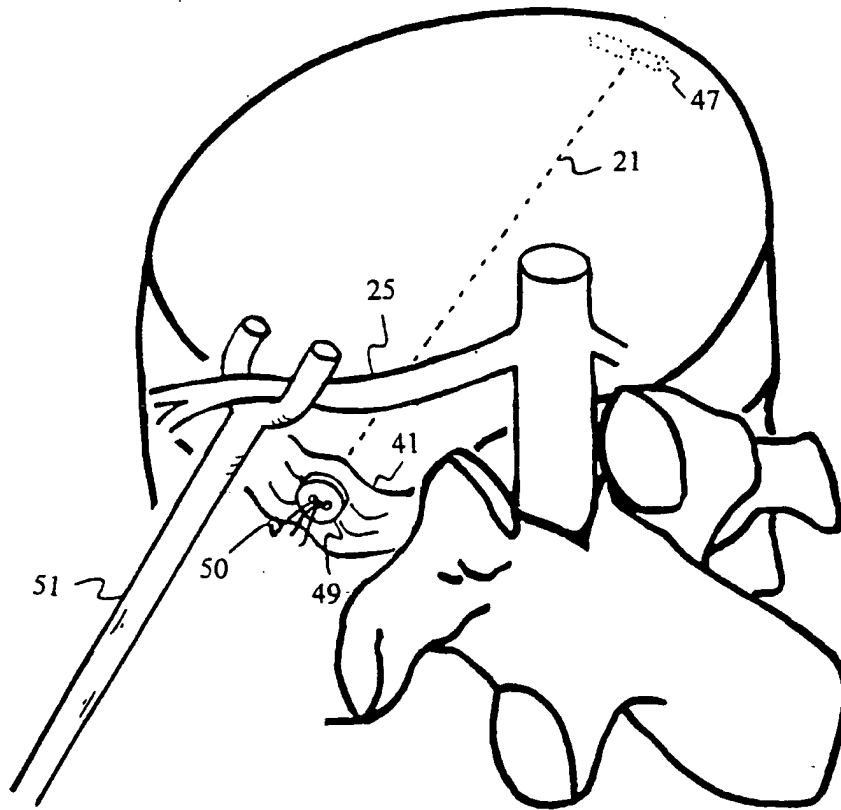


Figure 47

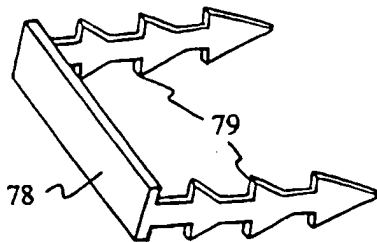


Figure 48

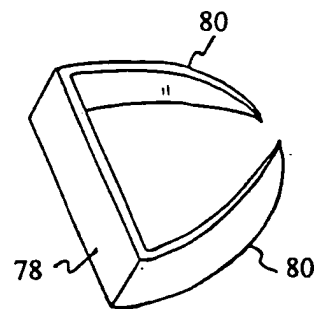


Figure 49

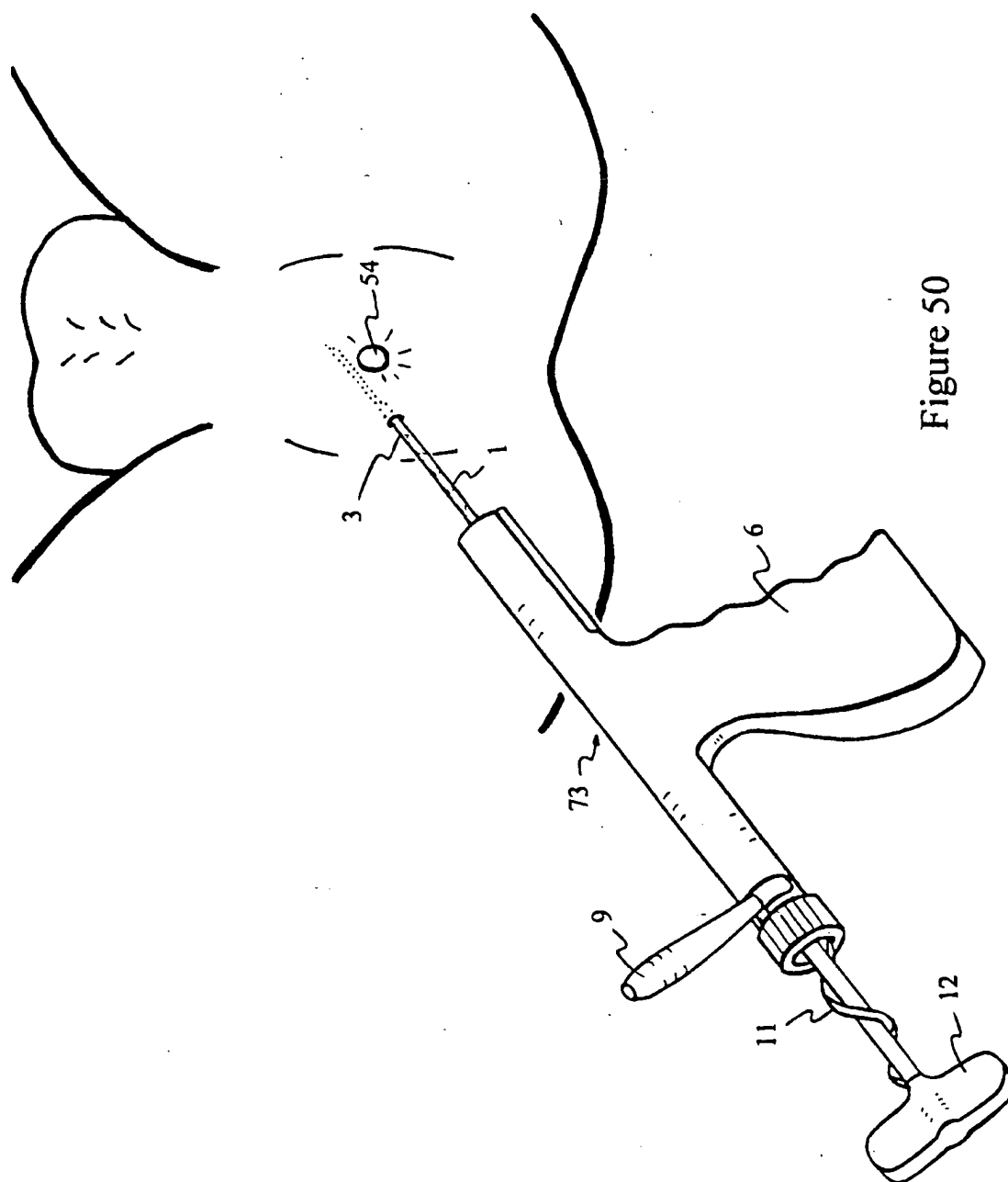


Figure 50

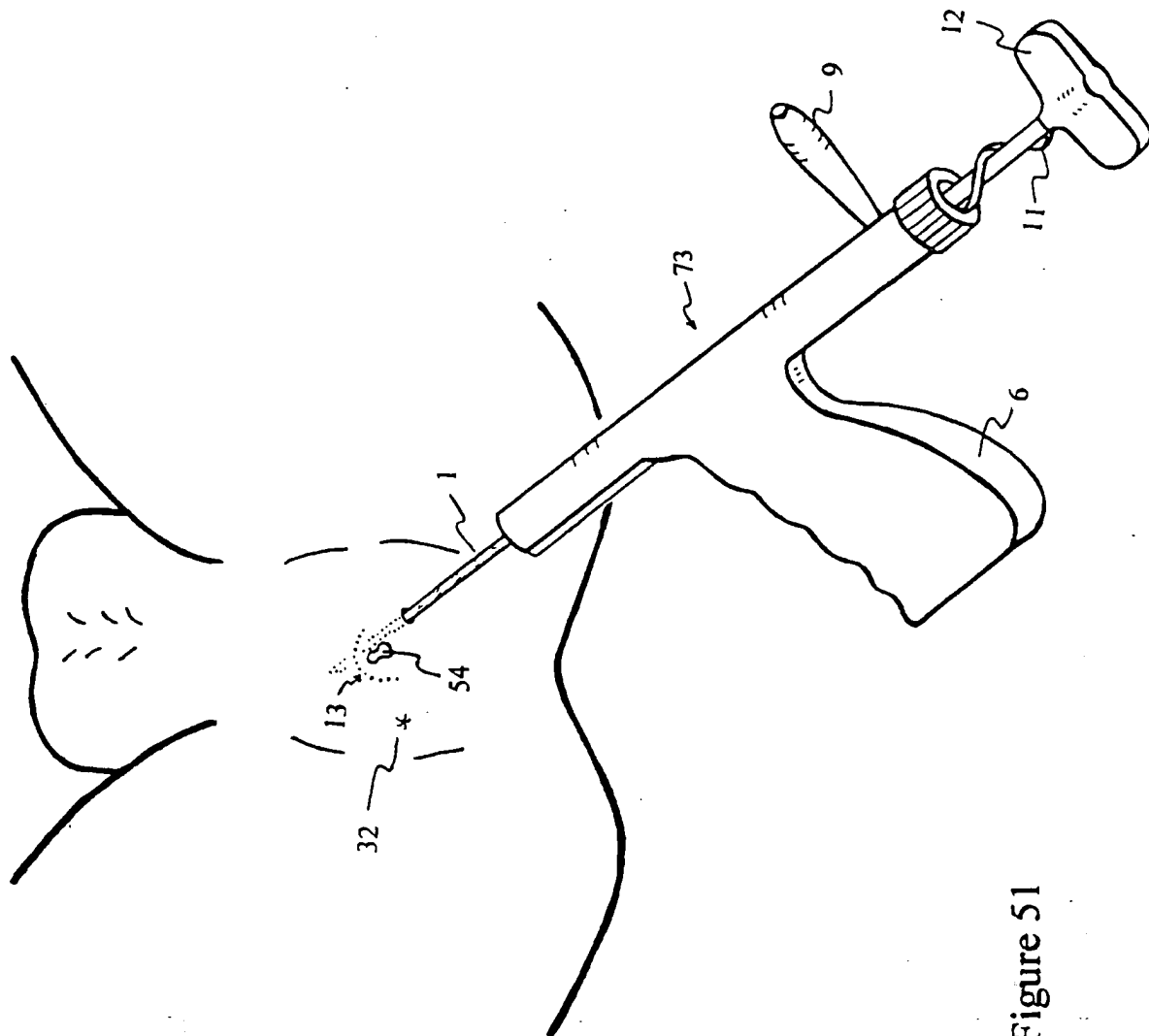


Figure 51

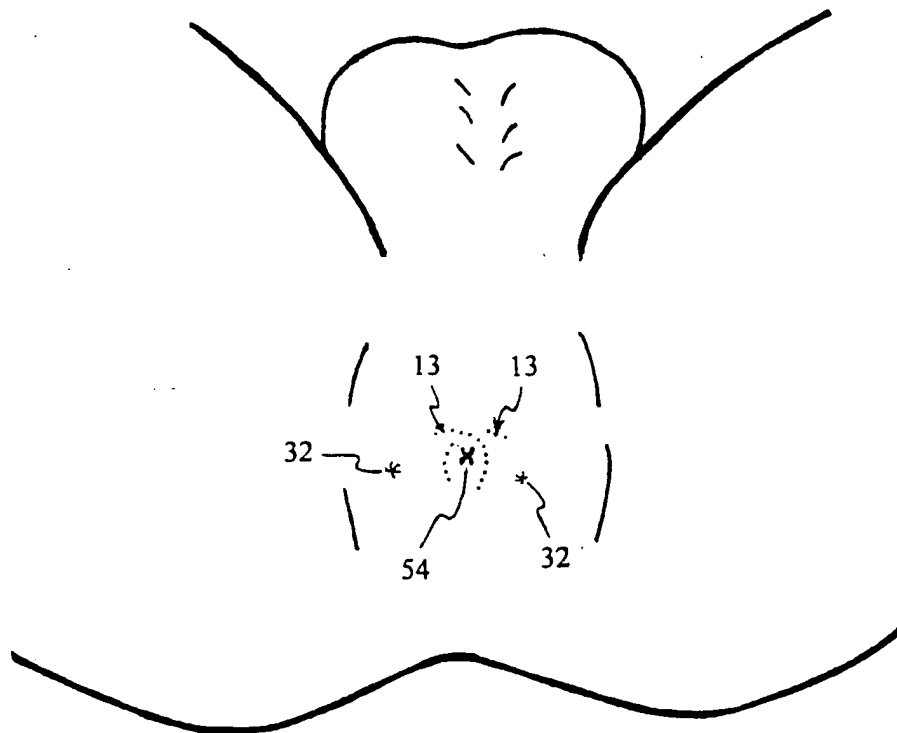


Figure 52



Figure 53A

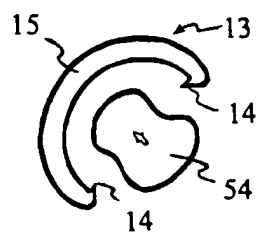


Figure 53B

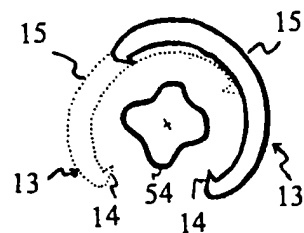


Figure 53C

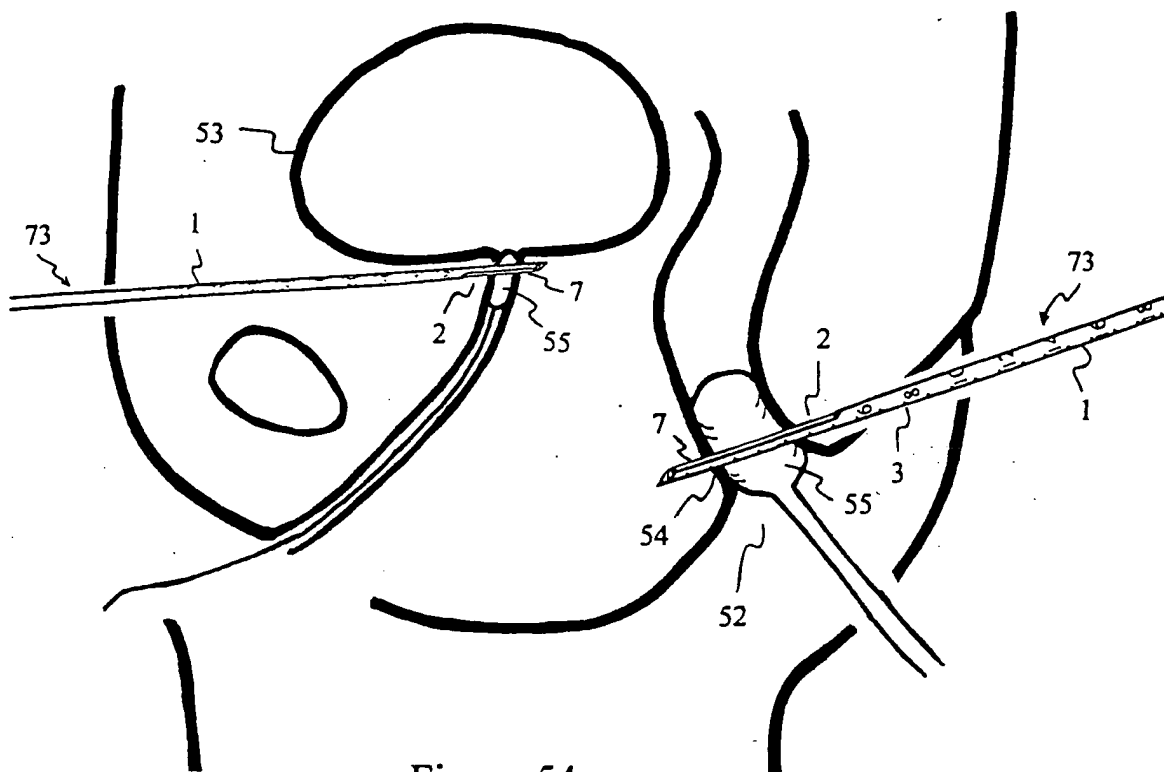


Figure 54

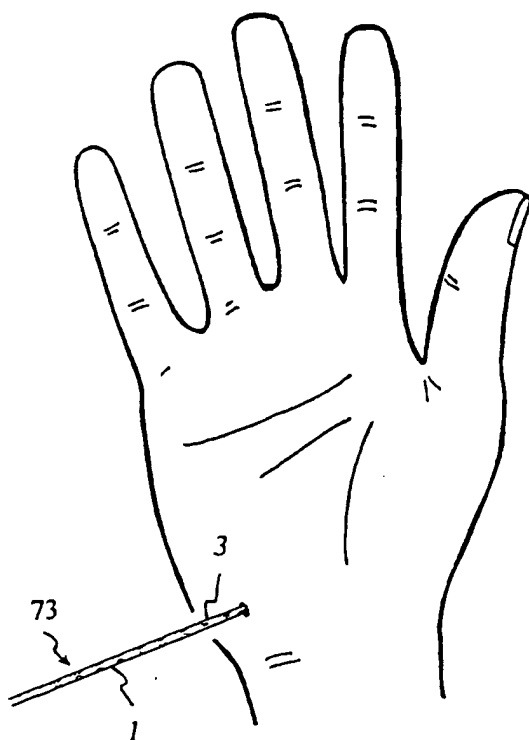


Figure 55

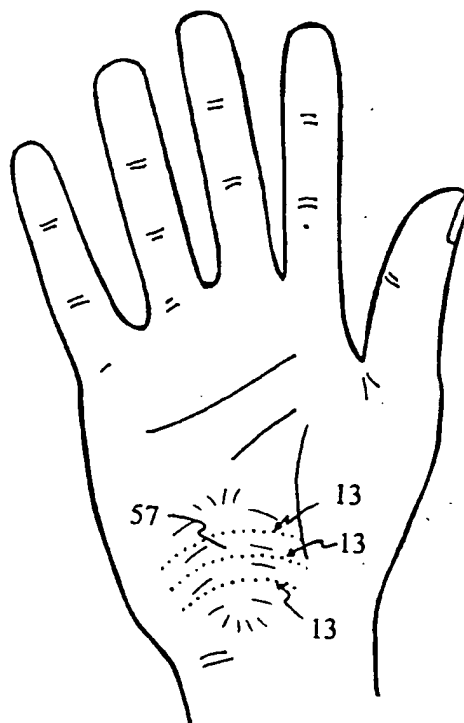


Figure 56

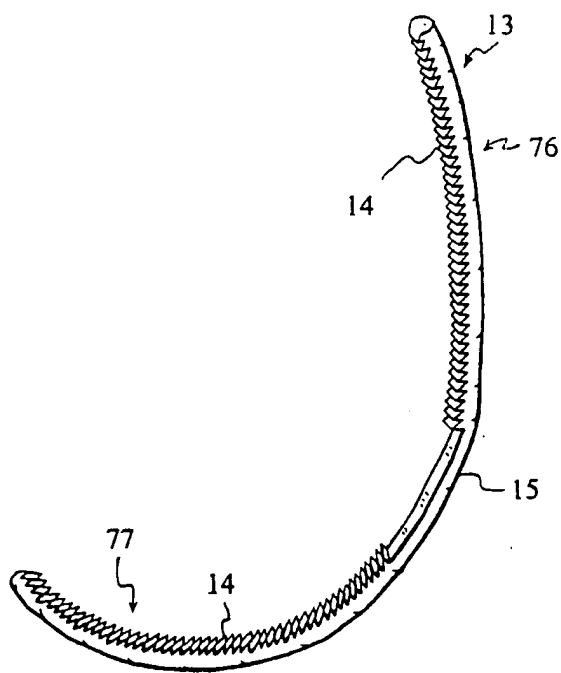


Figure 57A

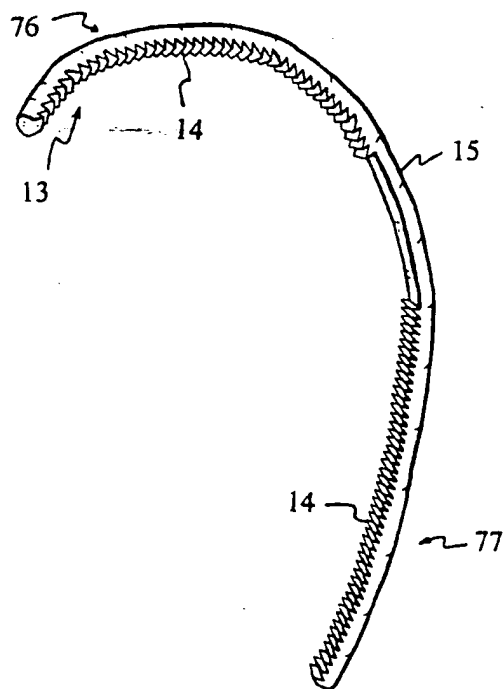


Figure 57B

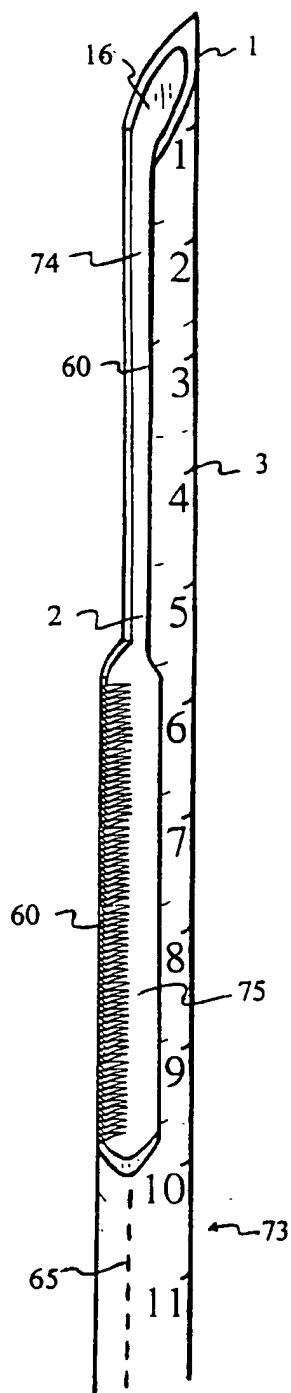


Figure 58

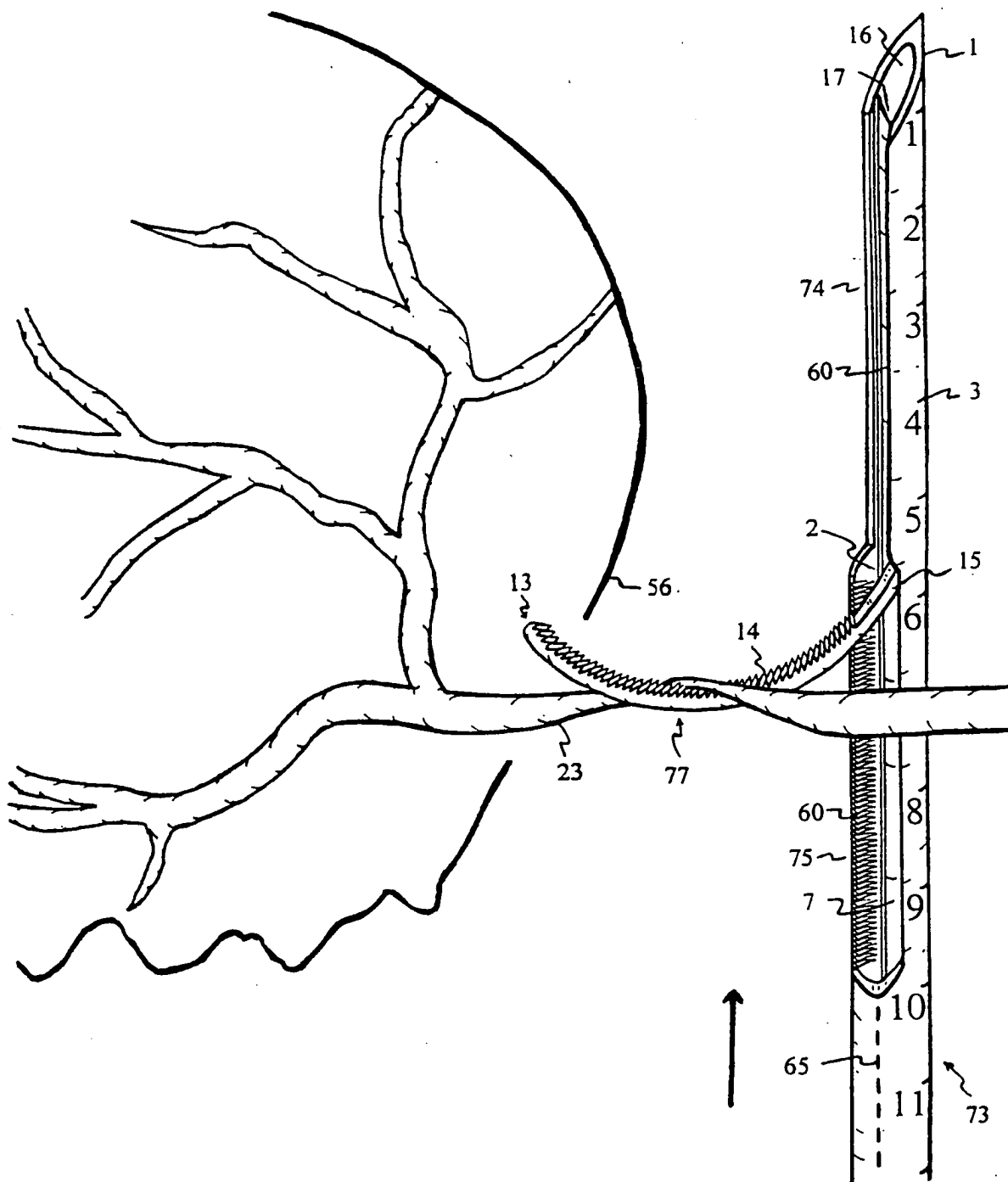
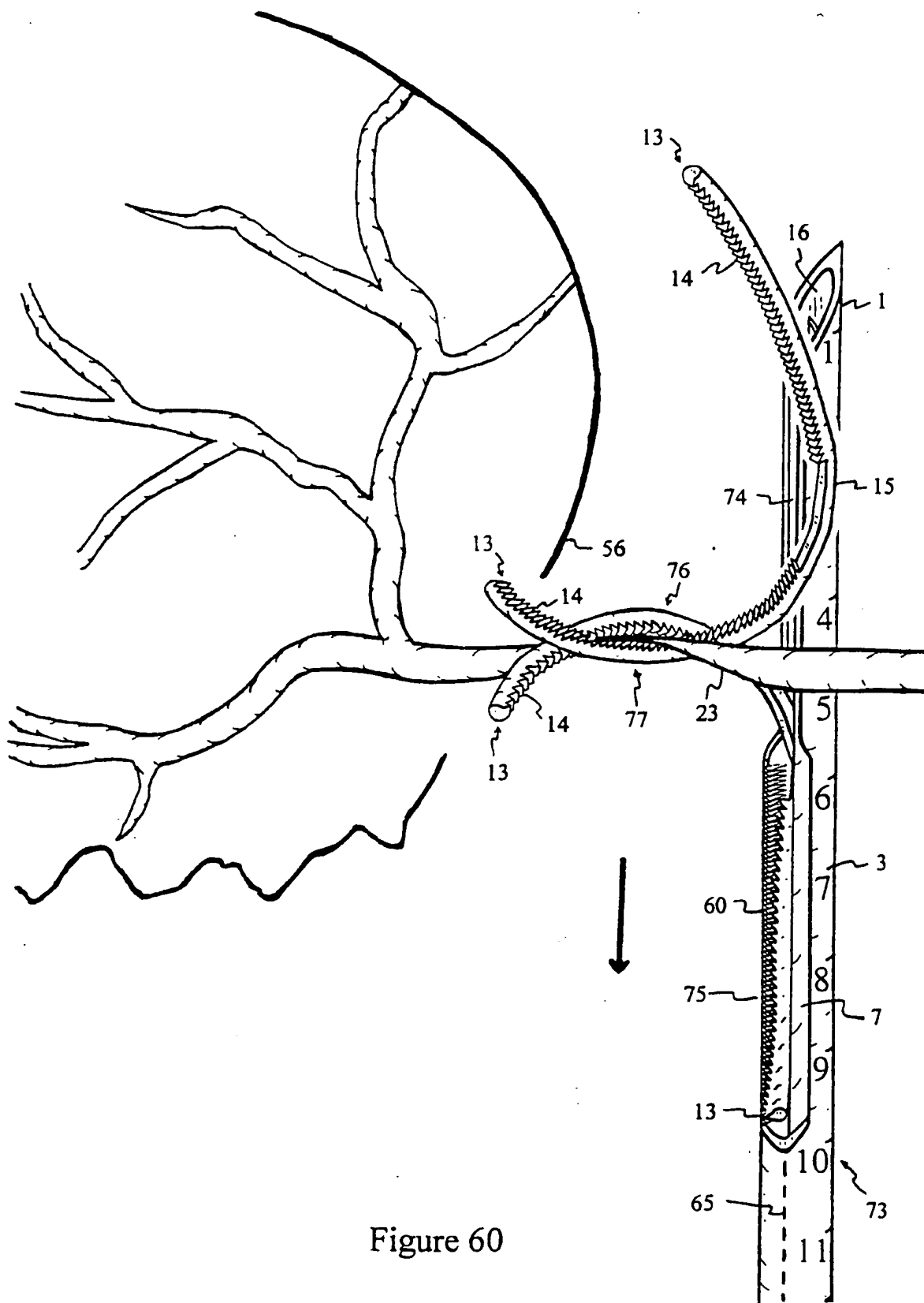


Figure 59



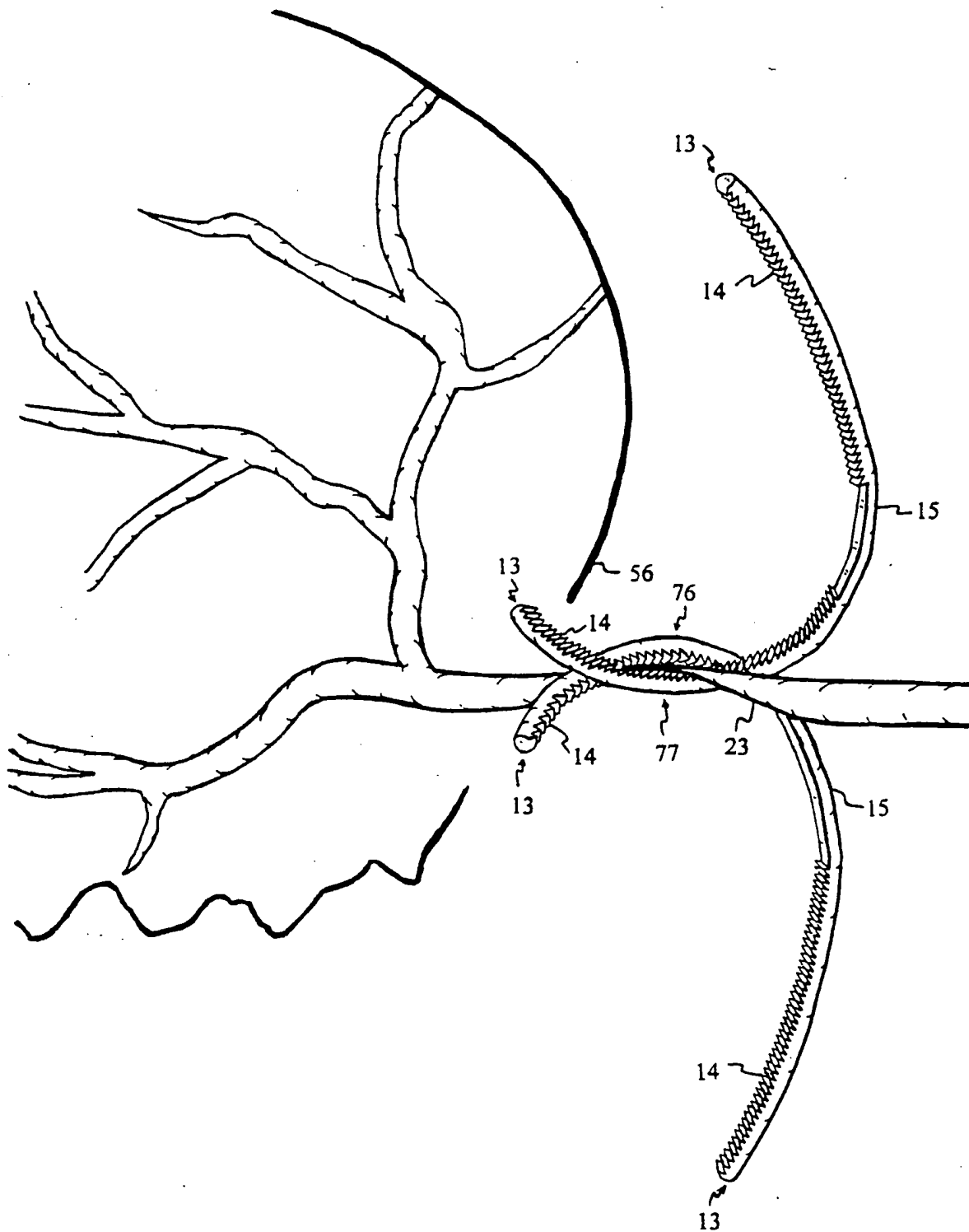


Figure 61

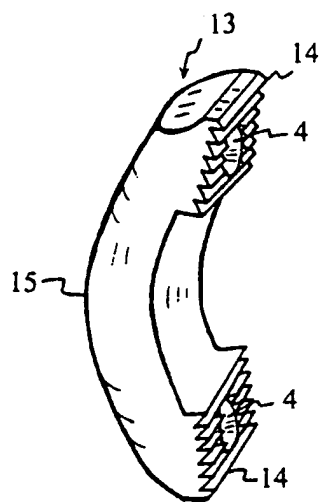


Figure 62

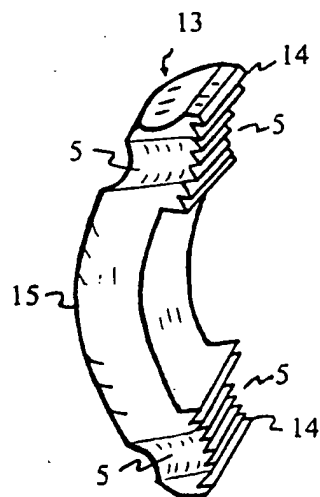


Figure 63

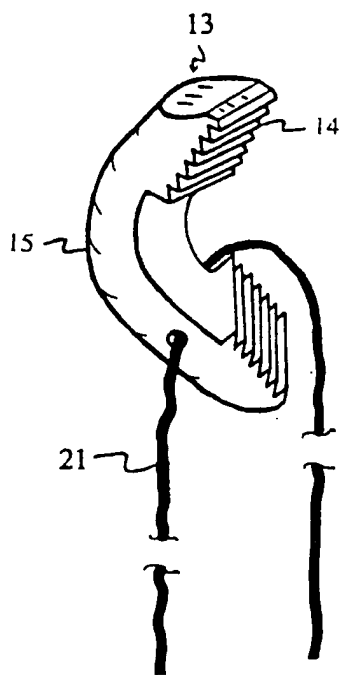


Figure 64

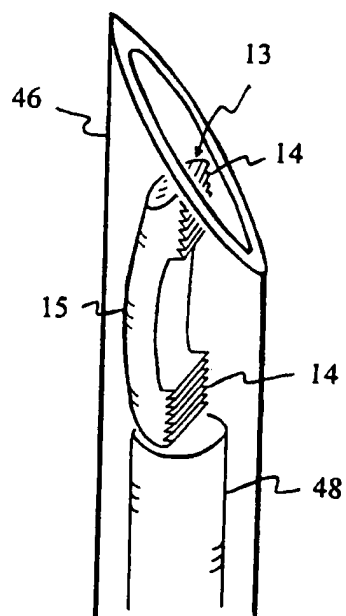


Figure 65

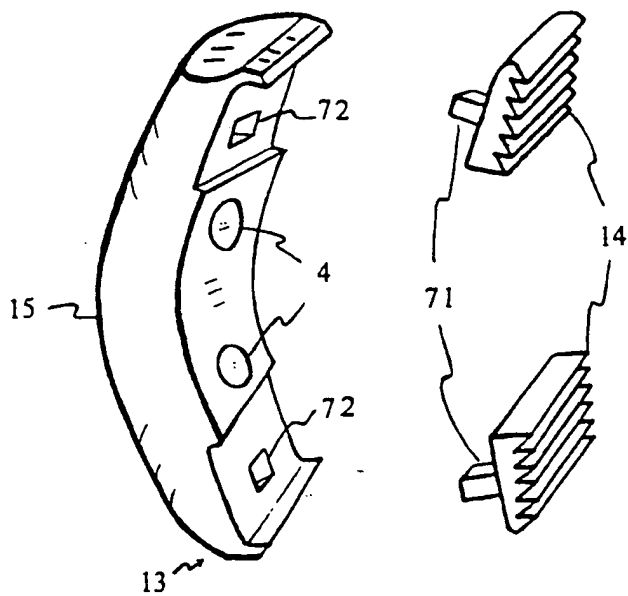


Figure 66

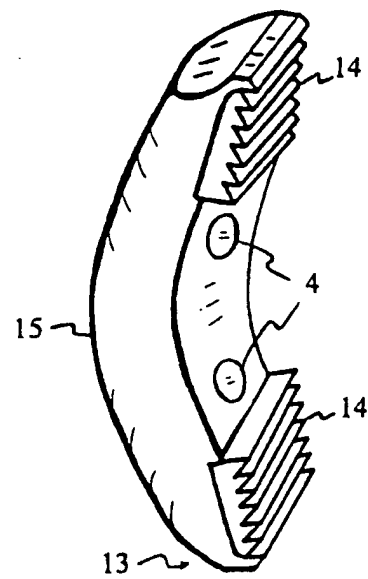


Figure 67

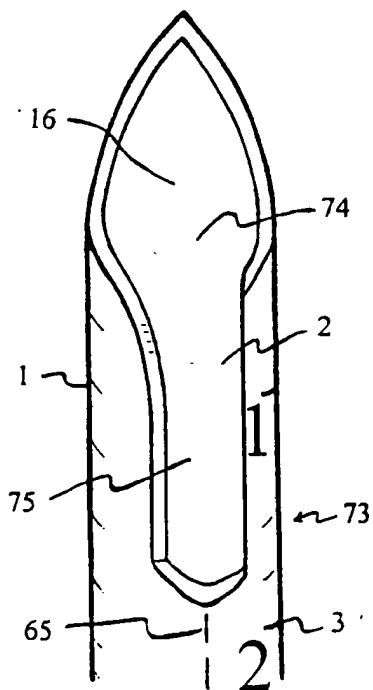


Figure 68

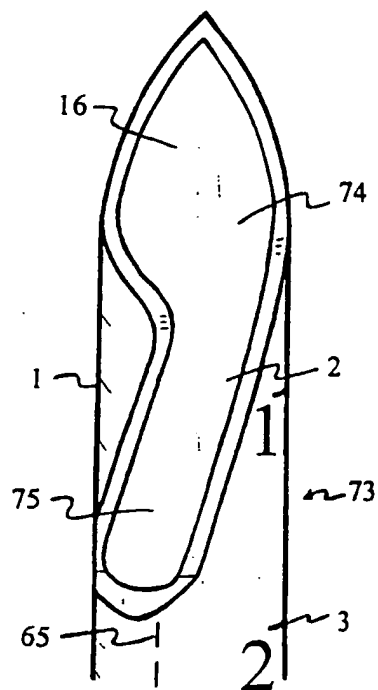


Figure 69

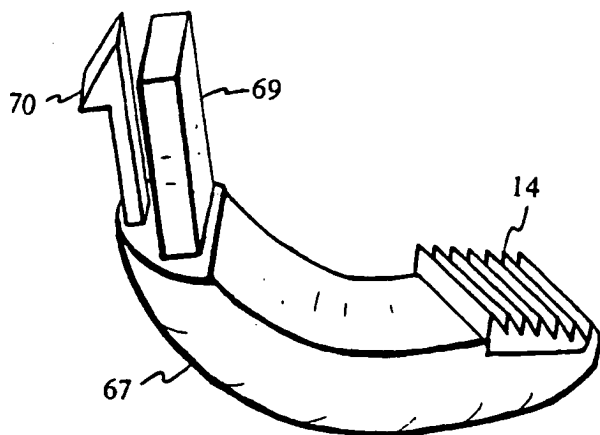
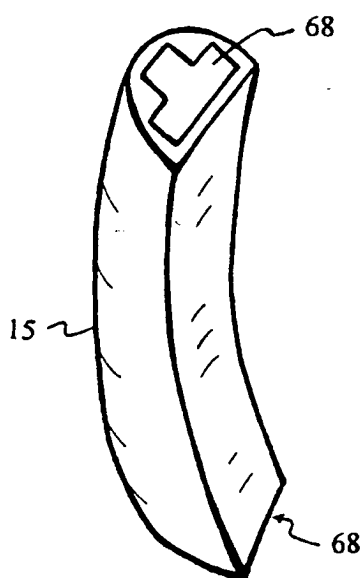
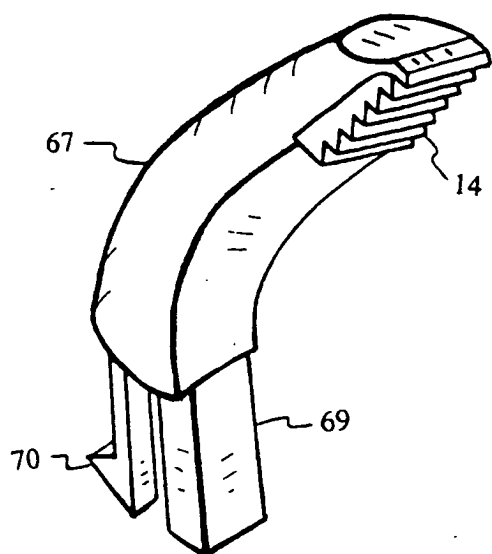


Figure 70

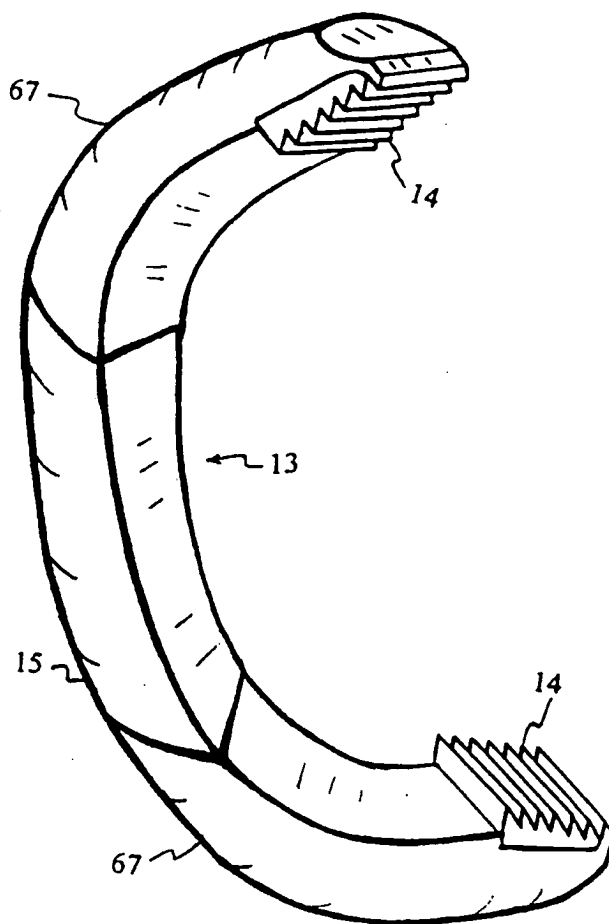


Figure 71

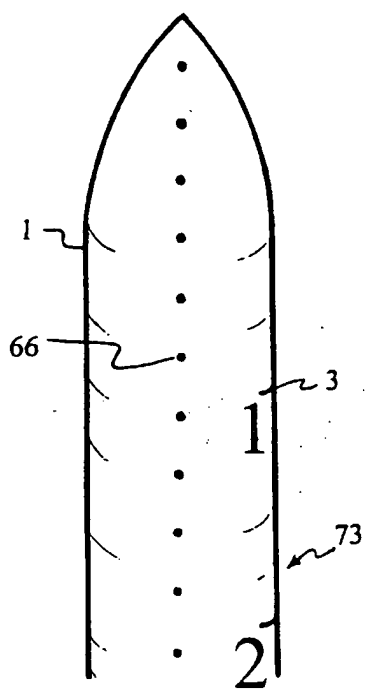


Figure 72

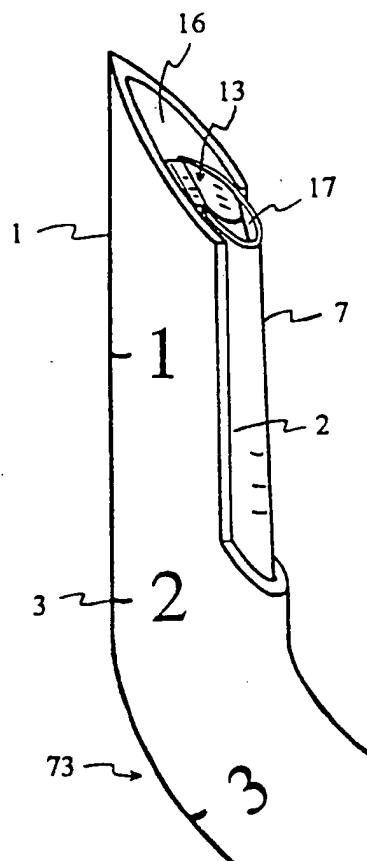


Figure 73

INTERNATIONAL SEARCH REPORT

Inter. Application No

PCT/US 99/21138

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/08 A61B17/064 A61B17/068 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 674 247 A (SOHN ZE EV) 7 October 1997 (1997-10-07) column 3, line 63 -column 4, line 25 ---	1,2,6,9, 10,17,18
X	WO 97 18762 A (INNOVASIVE DEVICES INC) 29 May 1997 (1997-05-29) page 11, paragraph 1; figures 1,17,18 -----	19,54
A		3,14,77



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the International filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

29 November 1999

Date of mailing of the international search report

06/12/1999

Name and mailing address of the ISA

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Authorized officer

Gérard, B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/21138

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 84-155
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/21138

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5674247 A	07-10-1997	IL 111985 A	11-04-1999
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WO 9718762 A	29-05-1997	US 5843084 A	01-12-1998
		AU 1055797 A	11-06-1997

(19) World Intellectual Property Organization
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4 September 2003 (04.09.2003)

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(10) International Publication Number
WO 03/071962 A2

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(22) International Filing Date: 31 January 2003 (31.01.2003)

(25) Filing Language: English

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60/359,394 25 February 2002 (25.02.2002) US

(71) Applicants and

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(81) Designated States (*national*): AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW.

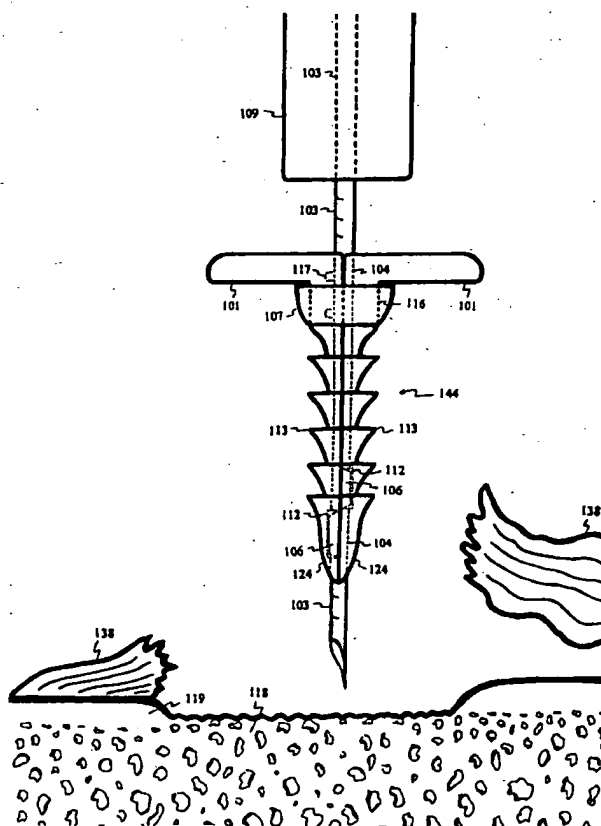
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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[Continued on next page]

(54) Title: **EXPANDABLE FASTENER WITH COMPRESSIVE GRIPS**



(57) Abstract: Anchoring elements of a fastener are made elastically curved. The curvatures of the elements are resiliently straightened by a trocar for tissue insertion. As the trocar is withdrawn, the anchoring elements resume the curved configuration, laterally pressing the elements against tissue to anchor the fastener.

WO 03/071962 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

EXPANDABLE FASTENER WITH COMPRESSIVE GRIPS

Jeffrey E. Yeung and Teresa T. Yeung

5

FIELD OF INVENTION

This invention is an expandable fastener delivered by a trocar or a needle into tissue. As the trocar is withdrawn, the fastener opens and anchors within tissue.

BACKGROUND

10 Tendon and ligament tears are common in sports injuries and trauma. Surgical repair of the tears can be invasive with many possible complications, including painful adhesions of scar tissue. Most patients are conservatively treated with immobilization. Only about 35% of orthopaedic trauma cases are treated surgically.

Many bone anchors have been studied and developed to reattach torn tissues. In general, metallic and non-degradable polymeric anchors or staples can fasten torn tissues
15 well; but with time, the non-degradable device can migrate into undesirable places, such as joints. On the other hand, SuretacTM is degradable and easily deployed; however failure due to low pull out strength is a common concern. US Patents 4,884,572 and 4,895,148 issued on December 5, 1989 and January 23, 1990 respectively by F. Barry Bays are related to a tissue repairing tack similar to SuretacTM in the market. The tack contains a
20 head, a cylindrical shaft with barbs and a lumen open from the head to the distal end of the shaft. For delivery of the tack, a needle is inserted into the lumen and protruded beyond the distal end of the shaft of the tack. The needle carrying the tack pierces through the torn tissue into bone. The barbs of the tack engage with bone tissue to hold the torn tissue in place. The needle is then withdrawn from the bone and the tack. The tissue
25 gripping strength of the barbs or threads of the tack is very limited, especially in poor quality bone. Therefore, the pull out strength of the tack is generally low. Healing of the torn tissue requires secure contact to the cancellous bone. The low pull out strength often contributes to tack loosening, forming a gap between the bone and supposedly reattached tissue. As a result, tissue reattachment is unsuccessful; weakness and pain persist.

30

SUMMARY OF INVENTION

Pull out strength is one of the most important criteria in biomechanical testing to evaluate the performance of a tack, staple, anchor or fastener. A new type of expandable fastener is made with elastically curved legs containing tissue-gripping elements. The legs contain semi-cylindrical troughs and trocar engaging rings or retainers. The elastically curved legs can be resiliently straightened and closed to form a shaft for tissue penetration. In the closed position, the semi-cylindrical troughs of the elastic legs form a lumen with the retainers aligned in series. A needle or trocar is inserted into the lumen through the aligned retainers to bind or link the elastically straightened legs; then the needle protrudes beyond the distal end of the expandable fastener. The trocar serves two functions: (1) to restrict or bind the elastic legs together and prevent them from opening, and (2) to spearhead the puncturing of tissue for delivering the expandable fastener. As the trocar is withdrawn from tissue and fastener, the elastic curvatures of the legs resume, pressing and anchoring the gripping elements laterally into the tissue.

15

REFERENCE NUMBERS

100	Intervertebral disc	118	Cancellous bone
101	Head of fastener	119	Cortical bone
103	Trocar, needle or K-wire	120	Counter junction
104	Trough, groove or lumen	121	Puncture hole
20 105	End plate	122	Suture
106	Trocar retainer or passage	123	Spinal cord
107	Assembly ring or clip	124	Expandable leg
108	Tack grips	128	Nucleus pulposus
109	Compressive sleeve	129	Facet joint
25 110	Peg hole	133	Drive
111	Disc compressor	144	Tack fastener
112	Indentation or recess	153	Marker
113	Gripping element	159	Vertebral body
116	Neck of fastener	160	Tissue ingrowth opening
30 117	Peg	161	Threaded portion

165	Step of a needle or trocar	278	Semiconic tip
168	Tongue	279	Sleeve
169	Groove	280	Distal end of compressive sleeve
174	Handle of driver	281	Recess for gripping element
5 175	Bridge of staple	282	Spine restrictive device
189	Socket	283	Hook & loop, or VELCRO™
194	Nerve	284	Screw fastener
196	Retractor	285	Counter-gripping fastener
235	Suture opening	286	Staple fastener
10 228	Phillips cross slot	287	Enlarged distal surface of sleeve
236	Screw thread	288	Inner surface of the bridge
276	Annular contact surface	289	Retainer or passage of staple
277	Base of double trocar		

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 depicts a side view of elastically curved pieces containing heads 101 and legs 124 above a ring 107 for composing an expandable tack fastener 144.

Figure 2 depicts the interior of the curved pieces with trocar retainers 106 arching over, and indentations 112 dipping beneath the longitudinal troughs 104.

Figure 3 shows the elastically curved legs 124 resiliently straightened to fit the trocar retainers 106 into the indentations 112.

Figure 4 indicates sliding of the ring 107 over the straightened legs 124 to restrain the neck 116 of the tack fastener 144. The joined troughs 104 form a lumen 104.

Figure 5 shows elastic opening of the curved legs 124 with the tightly fitted ring 107 holding the assembled tack fastener 144.

Figure 6 depicts a trocar 103 inserted into the lumen 104 of the tack fastener 144. A compressive sleeve 109 is loosely fitted over the trocar 103, positioned to press the tack fastener 144 into tissue.

Figure 7 shows a side view of the trocar 103 inserted into the lumen 104 through both trocar retainers 106 to keep the resilient legs 124 from spreading open.

Figure 8 depicts puncturing of the trocar 103 through a torn ligament 138 into bone 118, followed by compressive sleeve 109 pressing the tack fastener 144 into bone 188.

Figure 9 shows tacking of the torn ligament 138 by pressing the tack fastener 144 into the bleeding cancellous bone 118.

5 Figure 10 depicts trocar 103 withdrawal and elastic opening of the legs 124 to laterally press and fasten the gripping elements 113 into the porous bone 118.

Figure 11 shows an expandable tack fastener 144 with tack grips 108 on the underside of the head 101 to improve gripping power upon the ligament 138 or tacked tissue.

10 Figure 12 shows another three-piece assembled screw fastener 284 with self-tapping thread functioning as the gripping elements 113. The cross section of the head 101 is shown in Figure 13.

Figure 13 depicts the adjoining surfaces of the top and bottom pieces containing tongues 168 and grooves 169 with a Phillips cross-slot 228 on the screw head 101.

15 Figure 14 shows the fit between the tongues 168 and grooves 169 to prevent twisting between the top and bottom pieces during tightening of the screw fastener 284. The lumen 104 is extended into the screw fastener 284 from the bottom of the Phillips slot 228.

Figure 15 shows a trocar 103 protruding from the tip of a Phillips screwdriver 133.

20 Figure 16 shows the trocar 103 inserted through the screw fastener 284, binding the trocar retainers 106 together to keep the legs 124 from resiliently opening.

Figure 17 depicts a bulging disc 100 impinging upon a nerve root 194.

Figure 18 shows the screw fastener 284 holding a disc compressor 111 while advancing into the bulging disc 100.

25 Figure 19 shows bulge compression by the disc compressor 111 as the screw fastener 284 advances into the disc 100.

Figure 20 depicts medial repositioning of the disc compressor 111 toward the neuroforamen after initial bulge compression.

Figure 21 shows further advancement of the screw fastener 284 into the disc 100 by pressing in a large section of bulging anulus to free the nerve 194 from impingement.

Figure 22 depicts anchoring of the open legs 124 in the distal annulus to fasten the proximal bulge following withdrawal of the trocar 103 and driver 133.

Figure 23 shows another three-piece fastener 284 with a threaded portion 161 attachment and a nut 101.

5 Figure 24 shows the assembled fastener 284 tightened by the nut 101 over the threaded portion 161.

Figure 25 depicts a socket 189 and a trocar 103 protruding from the tip of a socket driver 133.

10 Figure 26 shows trocar 103 inserted through the lumen 104 holding both retainers 106, shown in Figure 24, to keep the legs 124 from resiliently spreading apart.

Figure 27 shows the screw fasteners 284 with threaded portion 161 being used as pedicle screws in the vertebral body 159.

Figure 28 shows a cross section of the screw fastener 284 with matching tongues 168 and grooves 169 on the adjoining surfaces.

15 Figure 29 shows engagement of the tongues 168 and grooves 169 bridging the adjoining surfaces to prevent twisting of the legs 124 during advancement into bone.

Figure 30 shows a three piece screw fastener 284 with curved legs 124 containing tongues 168 and grooves 169.

20 Figure 31 shows the legs 124 of the screw fastener 284, shown in Figure 30, glued and bound by a water degradable adhesive.

Figure 32 shows that the legs 124 of the screw fastener 284, shown in Figure 30, are externally tied or bound with degradable sutures 122 or band.

Figure 33 depicts a counter-gripping fastener 285 with four elastic legs 124 resiliently straightened by a trocar 103.

25 Figure 34 depicts a mid-longitudinal view of the fastener 285, as shown in Figure 33, with the trocar 103 linking the retainers 106 to keep the elastic legs 124 from opening.

Figure 35 shows the elastically curved legs 124 of the counter-gripping fastener 285 with trocar retainers 106 sized and configured to fit into opposing indentations 112.

30 Figure 36 indicates the assembly of the counter-gripping fastener 285. The ring 107, as shown in Figure 33, is used to cover and latch over the counter junction 120.

Figure 37 depicts a portion of a meniscus 135 with a tear 139.

Figure 38 shows bridging and fastening of the meniscal tear 139 by multiple counter-gripping fasteners 285.

Figure 39 depicts a sleeve 279 extending from the distal end 280 of a compressive sleeve 109.

Figure 40 shows the proximal legs 124 of the counter-gripping fastener 285 housed within the sleeve 279 to ease tissue insertion.

Figure 41 depicts puncturing of the sleeve 279 covered counter-gripping fastener 285 into a bulging disc 100, spearheaded by the trocar 103.

Figure 42 shows partial withdrawal of the needle 103 to open and fasten the distal legs 124 within the distal portion of the disc 100.

Figure 43 depicts pushing of the bulging anulus using an outer sleeve 279 having an enlarged distal end 287.

Figure 44 shows withdrawal of both needle 103 and compressive sleeve 109, while compression of the distal end 287 continues, to open and fasten the proximal legs 124 within the compressed anulus.

Figure 45 depicts bulge fastening by the counter-gripping fastener 285 within the disc 100, after retrieval of the outer sleeve 279.

Figure 46 shows a counter-gripping fastener 285 with distal and proximal gripping elements 113 independently operated.

Figure 47 depicts binding of the distal legs 124 in a closed position by a trocar 103 having a step 165 covered by a compressive sleeve 109.

Figure 48 depicts a sleeve 279 shielding and elastically compressing the proximal gripping elements 113 in a closed position.

Figure 49 shows penetration of the sleeve-covered-counter-gripping fastener 285 into a bulging disc 100.

Figure 50 depicts withdrawal of the sleeve 279, allowing the proximal gripping elements 113 to elastically open within and outside the anulus.

Figure 51 shows the stepped trocar 103 advancing the fastener 285 into the disc 100 and pushing the bulging layers of anulus inward by the proximal gripping elements 113.

Figure 52 depicts bulge fastening with the counter-gripping fastener 285 by withdrawing the stepped trocar 103 while holding the compressive sleeve 109 stationary. Then, the compressive sleeve 109 is also withdrawn.

Figure 53 shows a staple fastener 286 with two lumens 104 open from a bridge 175 through elastically curved legs 124 containing gripping elements 113.

Figure 54 shows the ridges and supports at the underside 288 of the bridge 175 and the lumens 104 extending to the distal ends of the legs 124.

Figure 55 depicts a double trocar 103 with semiconic tips 278 for inserting into the lumens 104 of the staple fastener 286, as shown in Figure 53.

10 Figure 56 shows trocar 103 insertion by sliding the semiconic tips 278 against the inner wall of the legs 124 of the staple fastener 286.

Figure 57 shows resilient straightening of the elastic legs 124 by the rigid trocars 103.

Figure 58 shows the distal tip of a leg 124 and a protruding trocar 103.

Figure 59 shows the interior side of the leg 124 with trocar 103 protruding beyond the
15 tapered distal tip of the leg 124 of the staple fastener 286.

Figure 60 shows a cross section of the leg 124 with a generally semi-circular lumen 104 and the outwardly facing rectangular gripping element 113.

Figure 61 depicts a bulging and herniated disc 100 impinging upon a nerve 194.

Figure 62 depicts the bulging layers of anulus and a channel of leaking nucleus
20 pulposus 128.

Figure 63 shows insertion of the double trocar 103 and delivery of the staple fastener 286 into the bulging and herniated intervertebral disc 100.

Figure 64 depicts further insertion of the trocars 103 without exiting the disc 100.

Figure 65 shows the compressive sleeve 109 pressing the bridge 175 and the bulge to
25 advance the legs 124 of the staple fastener 286 by sliding over the trocars 103.

Figure 66 depicts bulge fastening by withdrawing the trocars 104 to open and fasten the elastic legs 124 within the distal portion of the disc 100 while the compressive sleeve 109 continues to press against the bridge 175 and the disc 100.

Figure 67 shows the bulge compressed and fastened by the staple fastener 286.

Figure 68 depicts the result of the fastened disc 100: the bulging annulus is pressed in by the bridge 175 to alleviate nerve 194 impingement.

Figure 69 indicates a wide belt as a spine restricting device 282 to limit the mobility of the repaired vertebral 159 segment and protect the staple fastener 286.

5 Figure 70 shows posteriorly bulging disc 100 exposed after a laminotomy.

Figure 71 shows bulge compression and fastening by the bridge 175 of the staple fastener 286 to alleviate nerve 194 impingement.

Figure 72 shows normal bulging of a disc 100 responding to weight loading.

10 Figure 73 indicates a longitudinal cross-section of a normal vertebral segment responding to weight loading by bulging of the annular layers outward.

Figure 74 indicates diminishing nucleus pulposus 128 resulting in delamination of annulus within the degenerated disc 100.

Figure 75 shows swaying of the vertebral 159 segment caused by the degenerated disc 100.

15 Figure 76 indicates intervertebral instability above the facet joint 129.

Figure 77 indicates binding of the annular layers by the staple fastener 286 and restoring intervertebral stability to the repaired disc 100.

Figure 78 shows binding or linking the annulus of the repaired disc 100 by the staple fastener 286 to restore intervertebral stability.

20 Figure 79 indicates nerve 194 ingrowth into a degenerated disc 100, transmitting painful sensation during intervertebral instability.

Figure 80 shows nerve 194 ingrowth into a degenerated disc 100, transmitting painful sensations during bulging or bending of the annulus.

25 Figure 81 indicates atrophy of the ingrown nerve 194 due to prolonged compression of the staple fastener 286.

Figure 82 shows a staple fastener 286 with inwardly curved legs 124.

Figure 83 shows a staple fastener 286 with overlapping legs 124.

Figure 84 depicts trocars 103 insertion by sliding the semiconic tips 278 against the external walls of the inwardly curved legs 124 of the staple fastener 286.

Figure 85 shows resilient straightening of the inwardly curving legs 124 by the rigid trocars 103.

Figure 86 depicts repair of a broken bone 118 with the inwardly curved legs 124 of the staple fastener 286.

5 Figure 87 shows a one-piece elastically curved counter-gripping fastener 285 with a trough 104, trocar retainers 106 and gripping elements 113.

Figure 88 depicts the one-piece elastic fastener 285 being resiliently straightened by a trocar 103, deliverable by a compressive sleeve 109.

10 Figure 89 shows a side view of a three-piece resilient fastener 144, similar to the one in Figure 1, containing a suture 122 through suture openings 235.

Figure 90 shows the assembled fastener 144 containing the suture 122.

Figure 91 shows a trocar 103 linking both trocar retainers 106 of the left and the right pieces to resiliently straighten the legs 124 of the fastener 144.

15 Figure 92 depicts the leading trocar 103 and compression of the compressive sleeve 109 delivering the suture fastener 144 into a bleeding cancellous bone 118.

Figure 93 depicts components of a suture counter-gripping fastener 285 containing four elastically curved legs 124 similar to the components shown in Figure 35.

Figure 94 depicts resilient straightening of the legs 124 of the suture fastener 285 by inserting a trocar 103 through the retainers 106 in preparation for delivery.

20 Figure 95 depicts a needle 103 leading the suture counter-gripping fastener 285 puncturing and bridging a meniscal tear 139.

Figure 96 shows distal anchoring of the suture fastener 285 within the torn tissue by partial withdrawal of the needle 103 while the compressive sleeve 109 is held stationary behind the suture fastener 285.

25 Figure 97 depicts rejoining or approximating the torn portion with the main body of the meniscus 135 by pulling the suture 122.

Figure 98 shows complete withdrawal of the needle 103 to open and fasten the proximal legs 124. The compressive sleeve 109 is then also withdrawn to tightly fasten the tear 139. Excess suture 122 is then cut.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Although molding, casting or machining the expandable fastener as a single piece is possible, the expandable fasteners are assembled from individual parts to clarify the mechanisms and functions. In addition, the parts can be made with different materials to enhance performances of the expandable fasteners. Figure 1 depicts a side view of the three components of the expandable tack fastener 144. Two curved pieces or sections are made with elastic material containing generally semi-circular heads 101, necks 116 and legs 124 with outward facing gripping elements 113 and longitudinal troughs 104 or grooves in the interior sides. Figure 1 also shows pegs 117 protruding from the interior side of the right piece at the head 101 and neck 116 regions. In the interior side of the left piece, peg holes 110 are positioned, sized, and configured to fit the pegs 117. On both interior sides of the right and left legs 124, semi-cylindrical trocar retainers 106 or passages arch over the troughs 104. Adjacent to the retainers 106, indentations 112 or recesses are sunken into the trough 104. The indentation 112 on the right elastic piece is positioned, sized and configured to fit or house the retainer 106 on the left elastic piece and vice versa.

The inner dimension of a ring 107 or assembly retainer, as shown in Figure 1, is sized and configured to fit around the neck 116 region of the elastic pieces. Figure 2 depicts the interior sides of the components with trocar retainers 106 arching over the longitudinal troughs 104 adjacent to indentations 112 in the troughs 104. The arching retainers 106 enclose over portions of the troughs 104 to fit a trocar 103. The peg holes 110 on the left elastic piece are positioned, sized and configured to fit or house the pegs 117 on the right elastic piece.

Figure 3 shows assembly of the pegs 117 into the holes 110 by placing the interior sides of the left and right pieces together. Connection between the pegs 117 and holes 110 prevents slippage between the pieces and aligns the retainers 106 over the indentations 112. By compressing or closing the elastic legs 124 with an external force, the trocar retainer 106 of the right piece fits into the indentation 112 of the left piece and vice versa. In the closed position, the legs 124 are resiliently joined or straightened; the two semi-cylindrical troughs 104 are also joined together to form a cylindrical lumen 104.

Furthermore in the closed position, the ring 107 can slide over the gripping elements 113 onto the neck 116, as shown in Figure 4. Working in conjunction with the planted pegs 117, the tightly fitted ring 107 on the neck 116 prevents separation between the left and right pieces and retains the pegs 117 within the holes 110 to secure the assembled tack fastener 144. The head 101 and neck 116 regions can also be welded or glued together, without using the ring 107. If the external force were released, the elastic legs 124 would spread out, reestablishing the open, curved, deployed or predisposed position, as shown in Figure 5.

With the external force still straightening the legs 124, a trocar or a needle 103 is inserted into the lumen 104 from the head 101 and threaded through both retainers 106 and out past the distal ends of the legs 124, as shown in Figures 6 and 7. Figure 7 shows a side view of the trocar 103 inserted into the lumen 104 through both trocar retainers 106 to restrict the elastically curved legs 124 from spreading open. In essence, the trocar 103 serves as a removable linkage holding or latching the trocar retainers 106 of the expandable tack fastener 144 in a closed, delivery or straightened position. To optimize resilient closure or straightening of the legs 124, both retainers 106 are preferred to be located near the distal ends of the legs 124, as shown in Figure 7. The retainers 106 are also preferred to be positioned adjacent to each other to minimize bending of the trocar 103 by the opening forces of the elastic legs 124. Friction between the restrained retainers 106 and trocar 103 keeps the tack fastener 144 from sliding off the trocar 103. Beyond the distal ends of the closed legs 124, the protruding sharp tip of the trocar 103 spearheads tissue puncturing. A compressive sleeve 109 is loosely fitted over the trocar 103 as part of the delivery device for pressing the expandable tack fastener 144 into tissue. For a small surgical field and uneven surgical surface, the underside of the head 101 of the expandable fastener 144 can be contoured to fit over the tissue to be fastened. To avoid rotation of the tack fastener 144 around the trocar 103 during delivery, the lumen 104 of the tack fastener 144 and cross section of the trocar 103 can also be made non-round to improve control and precision for delivery. Figure 7 also shows a torn and detached ligament 138 over a burred or decorticated cancellous bone 118.

Figure 8 shows an initial trocar 103 puncture through a torn ligament 138 into bleeding cancellous bone 118, followed by compression of the sleeve 109 to deliver the straightened legs 124 of the expandable tack fastener 144 through the ligament 138 into the cancellous bone 118. Figure 9 shows tacking of the torn ligament 138 with the head 101 and securing of the legs 124 with gripping elements 113 into the bleeding cancellous bone 118. As the trocar 103 is withdrawn while compression of the sleeve 109 continues, the trocar restrainers 106 are no longer linked or bound together. Thus the legs 124 resiliently or elastically open, pressing the gripping elements 113 outwardly to fasten onto the porous cancellous bone 118, as shown in Figure 10. To prevent jamming between the retainer 106 and the indentation 112 or between the retainers 106, which would hinder the legs 124 from opening after withdrawal of the trocar 103, both distal and proximal ends of the retainers 106 are tapered, as shown in Figures 5 and 10. The compressive sleeve 109 is then withdrawn from the expanded tack fastener 144. The outward anchoring of the gripping elements 113 is elastic and continuously embeds and fastens into the tissue.

The interface between the reattached ligament 138 and the bleeding bone 118 will likely formed an adhesion, thus favoring permanent ligament reattachment to bone 118. Therefore, the expandable tack fastener 144 can be made with biodegradable material, which slowly degrades after the healing is complete. Figure 11 shows a tack fastener 144 with tack grips 108 at the underside of the head 101 to minimize movement of the tacked tissue, perhaps improving the healing rate of the tacked ligament 138 or tissue. The shape of the head 101 can also be modified to fit over the fastened tissue.

Outward anchoring is most intense at the distal ends of the legs 124, gradually decreasing toward the proximal ends to provide anchoring strength along the entire length of the legs 124 of the expandable tack fastener 144. The anchoring or fastening space created in the tissue between the curved legs 124 of the tack fastener 144 is cone-shaped, large at the base and small toward the surface, as indicated in Figure 10. In essence, the legs 124 of the deployed tack fastener 144 elastically flare open to establish a cone-shaped anchoring space within the tissue. The formation of the conical space alone within tissue would oppose pull out. Combined with the fastening of the outward pressing gripping elements 113 against the tissue within the conical space, the anchoring strength is

expected to be exceptionally high. The outwardly opening legs 124 of the expandable tack fastener 144 may be sufficient to anchor within osteoporotic bone or mushy tissue, whereas other anchors or suture may fail.

5 The tack fastener 144 may be able to be delivered without the sliding compressive sleeve 109. When the resiliently straightened legs 124 are inserted into the tissue, the tightness of the insertion provides some restriction upon the straightened legs 124, keeping the legs 124 together, as indicated in Figure 9. As a result, the friction between the trocar 103 and the retainers 106 substantially decreases, while the legs 124 are bound and surrounded by tissue. Furthermore, the gripping elements 113 of the legs 124 snag onto the tissue, 10 allowing the trocar 103 to withdraw and dislodge the tack fastener 144, possibly without holding the compressive sleeve 109 against the head 101. The trocar 103 can be modified by adding a step with a larger diameter to prevent the fastener 144 from sliding up and provide compression against the head 101 of the tack fastener 144 during delivery. The trocar 103 can also contain markers to indicate depth of insertion or penetration.

15 The expandable tack fastener 144 can be shaped to function as an expandable screw. Figure 12 shows another assembled three-piece screw fastener 284 with self-tapping threading as gripping elements 113. The screw fastener 284 also contains a lumen 104, trocar retainers 106 and indentations 112 in the elastically curved legs 124. The top of the head 101 contains a Phillips cross slot 228. The interior surfaces of the separated pieces 20 have tongues 168 and grooves 169, as shown in the top view in Figure 13, which prevent twisting between the pieces during tightening of the screw fastener 284. Other types of slots 228 for advancing the screw fastener 284 are possible. Figure 14 shows the fit between the tongues 168 and grooves 169 held together by the ring 107, as shown in Figure 12. The lumen 104 extends from the bottom of the Phillips slot 228 to the distal 25 end of the screw fastener 284. Figure 15 shows a trocar 103 protruding from the tip of a Phillips screw driver 133. The proximal end of the Phillips screw driver 133 contains screw thread 236 for tightening into a removable handle 174. In Figure 16, the elastically curved legs 124 of the screw fastener 284 are straightened into a closed position. The trocar 103 is inserted from the head 101 into the lumen 104, through both trocar retainers 30 106 to restrict the legs 124 from elastically opening, then out through the distal end of the

screw fastener 284. Insertion of the trocar 103 also helps to guide and position the driver 133 into the Phillips slot 228 to advance the screw fastener 284.

Figure 17 depicts a common nerve 194 impingement at the neuroforamen around the facet joint 129. Figure 18 shows the screw fastener 284 inserted through an elongated opening 165 of a disc compressor 111 and advanced into the bulging disc 100. The disc compressor 111 is designed to allow lateral adjustment with the elongated opening 165 for the screw fastener 284. For the comfort of the patient, the opening direction of the legs 124 is preferred to be in the plane of the disc 100, rather than opening and pressing toward the end plates 105 of vertebral bodies 159. A marker 153 on the driver 133 is aligned with the opening gap of the screw fastener 284 to identify the direction of leg 124 expansion. Figure 19 shows advancement of the screw fastener 284 through the nucleus pulposus 128 into the distal anulus of the disc 100 to compress the bulge with the compressor 111. The bulge compression opens up the neuroforamen to allow lateral to medial manipulation, positioning of the disc compressor 111 toward the neuroforamen, as shown in Figure 20. The screw fastener 284 is further advanced into the disc 100 to free the nerve 194 impingement by pressing in a large section of the bulging anulus, as shown in Figure 21. The trocar 103 with Phillips driver 133 is then withdrawn, allowing the unrestricted legs 124 of the screw fastener 284 to resume their curvatures, pressing and anchoring the gripping elements 113 into the relatively healthy and secured distal anulus, as shown in Figure 22. As a result, the bulging anulus is compressed and fastened to alleviate nerve 194 impingement. The compression and fastening of the bulging anulus may also collapse and seal leaking channels of the viscous nucleus pulposus 128 that cause neural irritation. The disc compressor 111 and the screw fastener 284 can be made with biodegradable material to treat nerve 194 impingement. As the degenerated anulus is compressed and metabolized, concurrently new anulus is shaped and formed under the compressor 111. After the disc 100 is healed, both the compressor 111 and screw fastener 284 then degrade to avoid possible device migration with time.

Figure 23 shows another screw fastener 284 having two elastically curved pieces with lumens 104, retainers 106, indentations 112, gripping elements 113 and semicylindrical threaded proximal portions 161. As the curved pieces join together, the threaded

proximal portions 161 form a cylindrical threaded portion 161. A nut with internal thread, sized to engage the cylindrical threaded portion 161, is used as head 101 of the screw fastener 284. Figure 24 shows the assembled screw fastener 284 tightened by the nut-like head 101 over the cylindrical threaded portion 161. Figure 25 shows a socket 189 and a
5 trocar 103 protruding from the tip of a socket driver 133. The elastically curved legs 124 are resiliently straightened, prepared for trocar 103 insertion. Sequentially, the trocar 103 enters through the socket 189, into the lumen 104 of the straightened fastener 284 and through the retainers 106 to bind the legs 124 in a straightened or closed position, and then protrudes out the distal end of the assembled fastener 284. The trocar 103 insertion
10 also guides the driver 133 to the socket 189 and the socket 189 over the nut-like head 101, as shown in Figure 26.

The screw fastener 284 with the threaded proximal portion 161 attachment and round contour of the nut-like head 101 is designed to be used as a pedicle screw. In a closed position, the expandable screw fastener 284 is advanced into the vertebral body 159 with
15 the socket 189 and driver 133. The trocar 103, socket 189 and driver 133 are then withdrawn to allow the legs 124 to resume the open position, pressing and fastening the gripping elements 113 into the vertebral body 159, as shown in Figure 27. Additional instrumentation for spinal fusion will be attached to the threaded proximal portion 161, then fastened with another nut, which will further secure the assembly of the screw
20 fastener 284 within the vertebral body 159. Expandable fastening can be particularly useful in poor quality bone.

To prevent lateral slippage between the legs 124 of the screw fasteners 284, as shown in Figures 12 and 24, during rotational tightening of the fastener 284 in the tissue, tongues 168 and grooves 169 can be incorporated longitudinally along both legs 124. The
25 longitudinally oriented tongues 168 and grooves 169 along the adjoining surfaces of the legs 124 are shown in cross-sectional view in Figure 28. In the closed position, the tongues 168 are entrenched in the grooves 169, as shown in a cross-sectional view in Figure 29.

Expansion of the screw fastener 284 or spreading of the legs 124 can be controlled
30 without the trocar 103, lumen 103, retainers 106 and indentations 112. The interior sides

or adjoining surfaces of the elastically curved legs 124, as well as the heads 101 and necks 116, contain matching tongues 168 and grooves 169, as shown in Figure 30. The adjoining surfaces of the curved pieces are glued and bound with a water degradable or soluble adhesive, while the ring 107 retains the tongue 168 in the groove 169 at the head 101 and neck 116 regions to hold the screw fastener 284 together, as shown in Figure 31. Welding or gluing with a water insensitive adhesive can also join the heads 101 and necks 116 of the elastic pieces without using the ring 107. After the screw fastener 284 is installed in tissue, the adhesive slowly degrades by blood serum, allowing the legs 124 of the fastener 284 to spread open and further fasten into tissue. The curved legs 124 can also be tied or bound together with degradable sutures 122, as shown in Figure 32, or with other degradable material.

Expandable fastener can also approximate and repair torn tissue by counter fastening. Figure 33 depicts an elastic counter fastener 285 with four legs 124 resiliently straightened by a trocar 103 with a compressive sleeve 109. Similar to the expandable tack fasteners 144 mentioned, each leg 124 contains an indentation 112 adjacent to a retainer 106 for linking onto the trocar 103, as shown in a mid-longitudinal view in Figure 34. Figure 35 shows two major pieces forming four elastically curved legs 124 with the trocar retainers 106 positioned, sized and configured to fit and match the indentations 112 on the adjoining piece. Both the indentation 112 and retainer 106 are preferred to be near the tip of each leg 124 to ensure adequate closure of the legs 124. The direction of the gripping elements 113 at the distal halves oppose the direction of the elements 113 at the proximal halves of the counter-gripping fastener 285. The gripping elements 113 at the distal halves of the fastener 285 oppose pulling, while the gripping elements 113 at the proximal halves oppose pushing. The distal and proximal groups of gripping elements 113 are separated by a counter junction 120. Within the counter junction 120, a retainer 106 is embedded in an indentation 112 like tongue and groove, as shown in Figures 34 to 36. The two-piece elastic fastener 285 is then tied and fastened by a ring 107 or a restricting member over the counter junction 120, as shown in Figure 33, to keep the retainer 106 in the indentation 112 and hold the mid-section of the counter-gripping fastener 285.

The needle 103 and compressive sleeve 109 are used in conjunction to deliver and deploy the counter-gripping fastener 285. The needle 103 carrying the fastener 285, as shown in Figure 33, punctures into a torn tissue to deliver the distal half of the fastener 285 through the tear 139, and places the counter junction 120 at the tear 139. In essence, the counter-gripping fastener 285 is bridging the torn tissue, over the tear 139. To deploy the counter-gripping fastener 285, the compressive sleeve 109 proximal to the fastener 285 is held stationary while the needle 103 is withdrawn. This allows the legs 124 to curve outwardly, as shown in Figure 36, pressing the gripping elements 113 into tissue at both distal and proximal sides of the tear 139. Figure 37 depicts a portion of a meniscus 135 with a tear 139. The fasteners 285 are delivered with counter junctions 120 positioned at or near the tear 139 of the meniscus 135. The needle 103 is then withdrawn from the puncture site 121 to allow both the distal and proximal legs 124 to counter-fasten the torn tissue, as shown in Figure 38. The counter-gripping fastener 285 is totally hidden within the repaired meniscus 135 with no protrusion to scrape, scratch or damage the delicate articular surface of the joint. Counter-fastening of the expandable fastener 285 is made possible by the opposing directions of the gripping elements 113 at the distal and proximal portions of the fastener 285 to rejoin or approximate the torn tissue for healing.

The counter fastener 285 may be able to be delivered without the sliding compressive sleeve 109. As the resiliently straightened legs 124 are inserted into tissue, tightness of the insertion provides restriction upon the straightened legs 124, keeping the legs 124 together. While the legs 124 are bound and surrounded by tissue, friction between the needle 103 and the retainers 106 substantially decreases. Furthermore, the gripping elements 113 of the legs 124 snag onto tissue, allowing the needle 103 to withdraw and dislodge the fastener 285 perhaps without holding the compressive sleeve 109 over the proximal end of the fastener 285 during needle 103 withdrawal. The needle 103 can be modified with a step, formed by an enlarged diameter, to provide compression onto the fastener 285 during delivery without the compressive sleeve 109. The needle 103 can also contain markers to indicate depth of penetration.

During tissue puncturing, the proximal gripping elements 113 of the counter-gripping fastener 285 may snag onto the tissue. Therefore, a sleeve 279 can be used to cover the

proximal legs 124, shielding the gripping elements 113 from tissue snagging during insertion. The sleeve 279 can be an extension from the distal end 280 of the compressive sleeve 109, as shown in Figure 39. To ease tissue insertion, the proximal legs 124 of the counter-gripping fastener 285 are housed within the sleeve 279 above the distal end 280 of the compressive sleeve 109, as shown in Figure 40.

The counter-gripping fastener 285 can be used to repair a bulging disc 100. The sleeve 279 covered fastener 285, as shown in Figure 40, is spearheaded by the trocar 103 as it punctures into the bulging annulus of the disc 100, as indicated in Figure 41. The trocar 103 is partially withdrawn, allowing the distal legs 124 of the fastener 285 to open and anchor into the distal portion of the disc 100, as shown in Figure 42. The bulging annulus is pressed inward by an outer sleeve 279 with an enlarged distal surface 287, as shown in Figure 43, or with another instrument. While the outer sleeve 279 continues to press against the bulge, the compressive sleeve 109 then trocar 103 are withdrawn, allowing the proximal legs 124 to open, pressing the gripping elements 113 into layers of the compressed annulus, as indicated in Figure 44. The compressed annulus is fastened or anchored by a series of gripping elements 113, holding the annulus in a non-impinging position even after compression of the outer sleeve 279 is withdrawn, as shown in Figure 45. The counter-gripping fastener 285 is totally hidden within the repaired disc 100 with no protrusion to impinge the nerve 194. Migration of the fastener 285 is expected to be greatly minimized by the counter-gripping mechanism of the elements 113 and opening of both distal and proximal legs 124. Furthermore, the counter-gripping elements can be made with degradable material, which lasts long enough to repair the disc 100, then degrades.

The distal and proximal gripping elements 113 of a counter-gripping fastener 285 can be operated independently. The counter-gripping fastener 285 is also made with elastic material. The distal legs 124 of the fastener 285 are operated by a trocar 103 similar to that of the counter-gripping fastener 285 mentioned in Figure 34. The proximal gripping elements 113 are elastically flared outward at an angle less than ninety degrees to trap, snag, hook, snatch or grab the surrounding tissue, as shown in Figure 46. The proximal gripping elements 133 are also designed to be resiliently pressed inwardly into adjacent

recesses 281. A stepped trocar 103 is inserted through a lumen 104 to restrict or bind the elastic distal legs 124 from opening, as shown in Figure 47. The step 165 of the trocar 103 is for pushing and advancing the counter-gripping fastener 285. A compressive sleeve 109 is positioned to slide over the stepped trocar 103. A sleeve 279 with penetration markers is used to restrict or maintain the proximal-gripping elements 113 in closed positions, as shown in Figure 48. Spearheaded by the stepped trocar 103, the counter-gripping fastener 285 is punctured into a bulging disc 100 with the sleeve 279 restricting and covering the proximal-gripping elements 113, as shown in Figure 49. When a proper depth into the disc 100 has been reached, the sleeve 279 is withdrawn while the stepped trocar 103 is held stationary to open the proximal-gripping elements 113. The first set of the elements 113 open between layers of the bulging anulus; and the second set of the gripping elements 113 open external to the bulging disc 100, as shown in Figure 50. The counter-gripping fastener 285 is further advanced into the disc 100 by pushing the stepped trocar 103. The first set of the opened elements 113 push against the inner layers of the bulging anulus toward the nucleus pulposus 128, as shown in Figure 51. The second set of the gripping elements 113 push the outer layers of the bulging anulus inward, as the distal legs 124 advance toward the distal edge of the disc 100. The stepped trocar 103 is withdrawn while holding the proximal end of the counter-gripping fastener 285 stationary with the compressive sleeve 109. The distal legs 124 elastically open, pressing the gripping elements 113 into the distal anulus of the disc 100 to counter fasten the inwardly compressed anulus with the proximal-gripping elements 113, as shown in Figure 52. Then, the compressive sleeve 109 is withdrawn from holding the proximal end of the fastener 285. As a result, nerve impingement is alleviated. The counter-gripping fastener 285, delivery device and method can be used endoscopically for a minimally invasive repair.

It may be possible to withdraw the stepped trocar 103 without using the compressive sleeve 109. When the resiliently straightened legs 124 of the counter-gripping fastener 285 are inserted into tissue, tightness of the insertion provides some restriction upon the straightened legs 124, keeping the legs 124 together, as indicated in Figure 51. As a result, the friction between the trocar 103 and the retainers 106 is substantially decreased,

while the legs 124 are bound and surrounded by the anulus. Furthermore, the gripping elements 113 of the legs 124 snag onto the tissue, which may allow the trocar 103 to withdraw and dislodge the fastener 285.

The expandable fastener 286 can also be made like a staple with elastically curved legs 124 containing lumens 104 inside and gripping elements 113 outside, as shown in Figure 53. The rectangular gripping elements 113 are designed to embed and fasten into tissue by elastic compression of the legs 124 to maximize the anchoring strength. The legs 124 are joined proximally by a bridge 175 with lumens 104 open from the bridge 175 leading to the distal ends of the legs 124. The bridge 175 contains tissue ingrowth openings 160 for securing or incorporating the staple fastener 286 into the fastened tissue. The inner surface 288 of the bridge 175 can be made smooth with a round contour to compress or with spikes to anchor the fastened tissue. The inner surface 288 can also contain ridges to fortify the bridge 175 and legs 124 of the staple fastener 286, as shown in Figure 54. Figure 55 depicts a double trocar 103, sized and configured for insertion into the lumens 104 of the staple fastener 286, as shown in Figure 53. To facilitate insertion and straightening of the elastically curved legs 124, the double trocar 103 is generally semicylindrical, tapered to semiconical 278 distal tips. During double trocar 103 insertion, the semicones 278 slide and glide along the inner walls of the legs 124 to avoid puncturing and snagging within the elastically curved legs 124 of the staple fastener 286, as shown in Figure 56. The inner walls of the curved legs 124 serve as trocar retainers 289 to restrain the elastic legs 124 from bending outwardly. In essence, the rounded sides of the distal ends of the trocars 103 facilitate insertion into the lumens 104 and straightening of the elastically curved legs 124. Figure 57 shows lumen 104 insertion of the rigid double trocar 103 to straighten the elastic legs 124 from a curved to a generally parallel or straightened position. A compressive sleeve 109 is designed to fit and slide over the shaft of the double trocar 103, also shown in Figures 55 and 57. The trocars 103 protrude beyond the distal tips of the legs 124 with the flat portion of the semicylindrical trocars 103 supporting the gripping elements 113 from beneath, as shown in Figure 58. The legs 124 of the staple fastener 286 are fortified by the double trocar 103 from within to prevent buckling or breakage during tissue insertion. The base 277 of the double trocar 103 and

the distal end of the compressive sleeve 109 are sized and configured to fit and press against the bridge 175 of the staple fastener 286. Figures 58 and 59 show the tapered distal end and retainer 289 of the leg 124 with the protruding semiconical 278 tip of the trocar 103 to facilitate or spearhead tissue insertion. The tapered ends and semi-circular cross section of the legs 124 and trocars 103 are designed to ease tissue puncture and reduce tissue trauma during delivery of the staple fastener 286. Figure 60 shows a cross-sectional view of the leg 124 with a generally semi-circular lumen 104 forming a half-ring like trocar retainer 289 and a flat support for the rectangular gripping elements 113 at the outer surface.

10 The double trocar 103 and the staple fastener 286 fit like a hand in a glove to straighten, protect, puncture and deliver the staple fastener 286. In summary, the double trocar 103 and the staple fastener 286 function as follows: (1) The semiconical 278 tips slide through the curved lumens 104. (2) The rigid trocars 103 straighten the elastically curved legs 124. (3) The trocars 103 fortify the legs 124 to prevent buckling or breakage during tissue insertion. (4) The exposed tips of the trocars 103 spearhead tissue insertion. (5) The base 277 of the double trocar 103 is positioned to press against the bridge 175 during tissue insertion.

The staple fastener 286 can be used to repair a bulging intervertebral disc 100. Figure 61 shows a herniated disc 100 impinging upon a nerve 194. Figure 62 shows a leaking channel of nucleus pulposus 128 within the bulging disc 100. Figure 63 shows the double trocar 103 spearheading penetration with the resiliently straightened legs 124 of the staple fastener 286 into the bulging disc 100. The curved base 277 of the double trocar 103, as shown in Figures 55 and 57, are sized and configured to fit and press the bridge 175 against the bulging anulus, as shown in Figure 63. Due to major blood vessels located antero-lateral to the spine, the trocar 103 protrusion through the disc 100 can potentially rupture the blood vessels. Therefore, under fluoroscopic view or other imaging, advancement of the trocars 103 stops prior to exiting the disc 100, as shown in Figure 64. The annular tissue distal to the distal ends of the legs 124 has already been punctured or carved open by the protruding tips of the sharp trocars 103 to allow further penetration by the tapered legs 124 of the staple fastener 286. Similar to the base 277 of the double

trocar 103, the distal end of the compressive sleeve 109 is also sized and configured to conform to the shape of the bridge 175 for pressing against the staple fastener 286. As the bridge 175 is pushed by the compressive sleeve 109, the remaining bulging annulus is pressed into the disc 100; and the legs 124 of the staple fastener 286 slide further along the double trocar 103 into the disc 100, as shown in Figure 65. Since the distal ends of the legs 124 are relatively blunt, the risk of blood vessel puncturing beyond the disc 100 is avoided. While the compressive sleeve 109 continues to press against the bridge 175 and the bulge, the double trocar 103 is withdrawn to allow the legs 124 to resume the elastic curvatures, as shown in Figure 66. The degenerated annulus of the disc 100 is compressed and compacted. As a result, the leaking channel of the viscous nucleus pulposus 128 may also be compressed, narrowed or even sealed by the disc 100 fastening, as indicated in Figure 66. The curvatures are greatest at the distal halves of the legs 124, pressing the gripping elements 113 into the relatively healthy and solid distal annular tissue to anchor and fasten the bulge, as shown in Figure 66. Due to the central location of the gel-like nucleus pulposus 128, the legs 124 of the staple fastener 286 might be able to straddle the nucleus pulposus 128 to grip the sturdy annular tissue. Regardless, the outward curvatures of the legs 124 will press and anchor onto annulus surrounding the nucleus pulposus 128, as shown in Figure 66. The length, size and/or curvature of the legs 124 can be varied with complementing trocars 103 to fit the anchoring sites and maximize the fastening strength of the staple fastener 286. Figure 67 depicts the result of the fastened disc 100 after withdrawal of the compressive sleeve 109. In Figure 68, the nerve 194 is lifted with a retractor 196 to show bulge compression by the bridge 175 of the staple fastener 286, which alleviates neural impingement and/or seals herniation.

Intervertebral disc 100 fastening with the staple fastener 286 may interfere with lateral bending, extension and/or flexion movements of the vertebral segment. During the initial two to six months after disc 100 fastening with the staple fastener 286, the patients can be fitted with a wide belt 282 fastened by VELCRO™ 283 or a buckle to limit vertebral motion, as shown in Figure 69. Limiting vertebral motion can prevent possible damage to the annulus or the staple fastener 286. After healing of the disc 100 and degradation of the staple fastener 286, normal range of motion and activity can then be resumed. The wide

belt 282 can also be used by patients with other disc 100 fastening devices, such as the screw fastener 284 shown in Figure 22 or counter-gripping fasteners 285 shown in Figures 44 and 52.

For disc 100 bulging within the central zone behind the lamina of the vertebral body 159, laminotomy is commonly performed to access the bulge, as shown in Figure 70. Instead of performing a discectomy following the laminotomy, the bulging anulus is compressed and fastened by the bridge 175 of the staple fastener 286 to alleviate nerve 194 impingement, as shown in Figure 71.

Concurrent with metabolism of the degenerated anulus, healthy and non-bulging anulus is shaped and formed under the bridge 175 of the staple fastener 286. The purpose of the staple fastener 286 is to (1) fasten the bulge to alleviate nerve 194 impingement, (2) seal the leakage of nucleus pulposus 128, (3) shape the newly forming anulus, and/or (4) degrade after healing of the disc 100.

The rate of degradation of various parts of the staple fastener 286 may be quite different and significant in terms of safety and efficacy of the staple fastener 286. Within the generally avascular disc 100, fluid exchange between the nucleus pulposus 128 and the end plates 105 of the sandwiching vertebral bodies 159, as shown in Figures 68 and 71, is quite limited. Therefore, the rate of hydrolysis/degradation of the legs 124 within the disc 100 is expected to be slower, perhaps much slower, than the rate of degradation of the bridge 175 located at the periphery of the disc 100. In essence, bulge anchoring with the compressive gripping elements 113 on the legs 124 is expected to outlast the compression of the bridge 175 of the staple fastener 286. It is unlikely to have erosion/degradation on both anchoring legs 124 causing the bridge 175 to break off and migrate into a nerve 194. Even if both anchoring legs 124 degrade before the bridge 175, the tissue ingrowth openings 160 on the bridge 175 are designed to trap or bind anular tissue, preventing detachment of the bridge 175 from the disc 100. The legs 124 of the biodegradable fastener 144, 284 or 286 can be coated with a water-repellent compound to reduce the rate of hydrolysis/degradation, thereby providing a durable anchoring support to the bridge 175 or head 101 of the fastener 144, 284 or 286.

The normal intervertebral disc 100 is designed to bulge slightly and resiliently to absorb the load upon the spine, as shown in Figure 72. Figure 73 indicates a mid-longitudinal view of the normal vertebral segment, responding to the weight from above by flexing the layers of anulus outward, resulting in normal bulging of the disc 100.

5 However, as the disc 100 degenerates, the internal support of the anular layers decreases, possibly corresponding to the diminishing water content of the nucleus pulposus 128. Recent research confirms the possibility of anular defects due to dehydration of nucleus pulposus 128. Studies show that anular unity is lost within cadaveric discs 100 with depleting nucleus pulposus 128. In fact, the anular layers of degenerated discs 100
10 delaminate or separate from each other, as shown in Figure 74.

Unlike patients with identifiable nerve 194 impingement, most low back pain patients show no radiographic evidence of disc 100 bulging or bone impairment, but continuously have unidentifiable and nonspecific pain. Experts believe that some of these patients may suffer from unstable motion segments (vertebral body-disc-vertebral body) caused by
15 degenerated discs 100. The unstable movement is called segmental instability. Segmental instability resembles an out-of-control car riding on a flat or partially deflated tire with unsupported sidewalls. The disc 100 with partially dried nucleus pulposus 128 is similar to the partially deflated tire. A routine vertebral motion could start swaying of the degenerative segment, as shown in Figure 75. The excessive movement from swaying of
20 the motion segment causes irritation, inflammation, strain and pain in surrounding ligaments and facet joints 129, as indicated in Figure 76. Treatment recommended for segmental instability is mostly rest and drug therapy, including analgesics, anti-inflammatory agents, oral steroids, muscle relaxants and/or antidepressants.

Expandable fasteners 284, 285 and/or 286 and methods used to fasten bulges, as
25 shown in Figures 22, 45, 52, 67 and/or 71 can also be used to minimize segmental instability of the degenerated disc 100. Bulge fastening using the expandable fasteners 284, 285 and/or 286 is accomplished by compressing or restricting the anular layers of the degenerated disc 100. Compression of the bridge 175 provides side support to the disc 100, as shown in Figures 67 and 77. Similarly, the disc compressor 111 also provides side
30 support to the disc 100, as shown in Figure 22. Layers of anulus are linked, fastened, tied

and/or unified by the anchoring legs 124 of the expandable fasteners 284, 285 and/or 286 to promote rigidity and stability within the degenerated disc 100, as shown in Figures 22, 45, 52, 67, 71, 77 and/or 78. Furthermore, insertion of the legs 124 of the expandable fasteners 284, 285 and/or 286 also provides bulk and cushion within the disc 100 to
5 reduce compressibility and instability of the degenerated disc 100.

By adding bulk within the discs 100 and consolidating the bulging annulus, the expandable fasteners 284, 285 and/or 286 in Figures 22, 45, 52, 67 and/or 71 may also thicken the degenerated discs 100 to alleviate nerve 194 impingement from spinal stenosis.

Chronically degenerated discs 100 can induce ingrowth of sinuvertebral nerves 194
10 into the annulus, emitting pain signals within the disc 100 during swaying, as shown in Figure 79, and bulging, as shown in Figure 80. Sinuvertebral nerves, which normally grow only on the surface, extend well into the disc 100 when it is degenerating. The staple fastener 286 in Figure 78, or the compressor 111 in Figure 22 can compress the sinuvertebral nerves 194 at the surface of the disc 100 causing the nerve 194 to atrophy,
15 thus ceasing or interrupting the signals of pain transmitted within the degenerated disc 100.

The legs 124 of the staple fastener 286 can also be elastically and inwardly curved with lumens 104 opened into and through the curved legs 124, as shown in Figure 82. The inward curvature can be further intensified by overlapping the legs 124 and placing the
20 legs 124 in different planes, as shown in Figure 83. The outwardly facing semicones 278 of the double trocar 103 straighten the inwardly curved legs 124, as shown in Figure 84. During insertion of the trocars 103, the semicones 278 slide and glide along the outer wall of the legs 124 to avoid puncturing and snagging within the elastically curved legs 124 of the staple fastener 286, as shown in Figure 84. The outer walls of the curved legs 124
25 serve as trocar retainers 289, to restrain the elastic legs 124 from bending inwardly. Figure 85 shows straightening of the elastic legs 124 by the rigid trocars 103, from a curved to a generally parallel position for delivery. In essence, the round or blunt sides of the tips of the double trocar 103 facilitate insertion into the lumens 104 and straightening of the elastically curved legs 124. The base 277 of the double trocar 103 is sized, shaped
30 and configured to fit and compress the bridge 175 of the staple fastener 286. Similar to

the outwardly opening staple fastener 286, the double trocar 103 protects, strengthens and delivers the inwardly opening staple fastener 286. The sharp distal tips spearhead tissue puncturing, and the base 277 presses against the bridge 175 to drive the legs 124 of the staple fastener 286 into tissue, such as broken bone 119. As the resiliently straightened
5 legs 124 insert into tissue, tightness of the insertion provides restriction upon the straightened legs 124, keeping the legs 124 in a parallel position. As a result, the friction between the double trocar 103 and the retainers 289 substantially decreases, while the legs 124 are bound and surrounded by the tissue. Furthermore, the gripping elements 113 of the legs 124 snag onto the tissue, allowing the double trocar 103 to withdraw and dislodge
10 the staple fastener 286. Therefore, the staple fastener 286 may be able to be delivered with or possibly without the compressive sleeve 109. Figure 86 shows fastening of the broken bone 119 with the bridge 175 anchored externally and the gripping elements 113 internally onto cancellous bone 118 to hold the broken 139 junction closed.

Elastic fastening provides superior anchoring strength to approximate torn 139 tissue.
15 The legs 124 of the staple fastener 286 are delivered straight into the tissue with the bridge 175 pressing against the surface. As the double trocar 103 is withdrawn from the staple fastener 286, the legs 124 resume the predisposed elastic curvatures to (1) press the gripping elements 113 into tissue, and (2) approximate the torn tissue 139 through elastic closure. As a result, the elastically fastened tissue is likely to provide no gap at the torn
20 junction for proper and quick healing.

Multiple staple fasteners 286 can be made connected to each other, separated by perforations. The connected staple fasteners 286 form a strip, as the staples for papers, loading into a stapler equipped with double trocar. The strip of staple fasteners 286 is compressed by a spring in the stapler, positioning one staple fastener 286 at a time under
25 the double trocar for delivery. In one downward stroke, the double trocar inserts into the lumens 104, straightens the elastically curved legs 124, breaks off the positioned staple fastener 286 from the strip, punctures into tissue and compresses the bridge 175 with the base to deliver the staple fastener 286. As the resiliently straightened legs 124 insert into tissue, tightness of the insertion provides restriction upon the straightened legs 124,
30 keeping the legs 124 in a parallel position. While the parallel legs 124 are bound and

surrounded by the tissue, the friction between the double trocar and the retainers 289 substantially decreases. Furthermore, the gripping elements 113 of the legs 124 snag onto tissue, allowing the double trocar to withdraw and dislodge the staple fastener 286. The returned double trocar is ready to deliver another staple fastener 286 advanced by the
5 spring in the stapler. To ensure proper dislodging of the fastener 286, a compressive sleeve can also be used to hold the bridge 175 of the staple fastener 286 while the double trocar withdraws. The compressive sleeve can slide over the base of the double trocar. It is also possible to compress the staple fastener 286 with a plunger extending from the base of the double trocar. Operation of the double trocar, compressive sleeve or the plunger
10 can be motorized, air-driven or manual.

The staple fasteners 286 can also be used to repair soft tissue. The degradable staple fastener 286, as shown in Figures 83, 82 and/or 53, may be effective in treating pneumothorax of the punctured lung by sealing air leak into the pleural space.

Counter tissue fastening can also be accomplished with a one-piece elastically curved
15 fastener 285 with a trough 104, trocar retainers 106 and gripping elements 113, as shown in Figure 87. In Figure 88, the one-piece elastic fastener 285 is resiliently straightened by a trocar 103 and ready to be delivered by a compressive sleeve 109. The delivery of the one-piece fastener 285 is similar to the procedure used for the counter fastener 285 depicted in Figure 33.

20 The expandable tack fastener 144 can also be used as a suture fastener 144. Components of a suture fastener 144 depicted in Figure 89 are slightly modified from the components of the tack fastener 144 mentioned in Figure 1. The modified tack fastener 144 contains openings 235 for passing a suture 122 and a small head 101. The assembled suture fastener 144, as shown in Figure 90, is in an open position with the elastic legs 124
25 spread apart. To deliver the suture fastener 144, the elastically curved legs 124 are resiliently straightened with the retainers 106 positioned within the indentations 112. The legs 124 are then held in the closed position by linking the retainers 106 with the trocar 103, as shown in Figure 91. The suture fastener 144 is delivered into cancellous bone 118 by the trocar 103 and compressive sleeve 109, as shown in Figure 92, to reattach a torn
30 ligament 138. The trocar 103 and compressive sleeve 109 are then withdrawn, allowing

the elastic legs 124 to open and fasten within the bone 118. The suture 122 is used to fasten and reattach the ligament on the cancellous bone 118. The suture fastener 144 can also anchor in soft tissue, especially for minimally invasive or endoscopic surgery.

The counter fastener 285, as shown in Figure 33, can also become a suture fastener 285 by attaching a suture 122. Figure 93 depicts the components of a suture fastener 285, similar to the one shown in Figure 35. A suture 122 is threaded through suture openings 235 of the counter fastener 285. Joining of retainer 106 to indentation 112 serves as tongue and groove at the midsection of the suture counter fastener 285. In the open position, the distal legs 124 compress and anchor the gripping elements 113 into tissue to resist pull out. The proximal legs 124 wedge open, trapping and anchoring tissue between the interior sides of the proximal legs 124. Unlike tissue counter fastening, the gripping elements 113 on the proximal legs 124 are not crucial for suture 122 fastening. The anchoring strength of the suture 122 is from the gripping elements 113 on the distal legs 124 and tissue wedged between the proximal legs 124. A ring 107 or other restrictive means can be used to fasten the midsection of the elastic components. The tension of the suture 122 also holds the elastic pieces of the fastener 285 together. Figure 94 depicts resilient straightening of the elastic legs 124 of the suture fastener 285 by inserting a trocar 103 through the retainers 106 in preparation for delivery. Delivery of the suture fastener 285 is similar to that of the counter fastener 285. Spearheaded by the trocar 103, the suture fastener 285 punctures and enters into the tissue. Markers on the compressive sleeve 109, as shown in Figure 94, indicate depth of tissue penetration. When the proper depth is reached, the trocar 103 is withdrawn while the compressive sleeve 109 is held stationary to deploy the suture fastener 285 into tissue. The elastic and unrestricted legs 124 open and fasten within tissue, anchoring the suture 122 for various repairs.

Closure and healing of meniscal tears 139 are challenged by the pressure between bones and lack of blood supply within most of the meniscus 135. The meniscus 135 is the cartilaginous cushion between constantly rubbing condyles of the femur and tibia. Only the outer quarter to one-third of the meniscus 135 is vascularized with significant possibility of healing. After surgical repair, if a gap is created at the supposed closure by rubbing and/or pressure between the condyles, healing is unlikely and pain persists. Due

to the elastic curvatures of the counter-fastening legs 124, the gripping elements 113 are pressed into the meniscal tissue 135 to provide superior fastening strength to secure and maintain the closure of the tear 139. Unlike repair with suture or prior art devices, the counter-gripping fasteners 285 are totally concealed within the meniscus 135 to prevent scraping or scratching of the delicate articular cartilage of the condyles, which can lead to irreversible damage to the joint. The counter-gripping fasteners 285 can be made with degradable material to approximate and heal the tear 139, then degrade to avoid migration or potential exposure at the joint.

The attached suture 122 on the counter-gripping fastener 285 can also manipulate, reposition or tighten a repair. A counter-gripping fastener 285 with an attached suture 122, similar to the one in Figure 94, is used to puncture and bridge a meniscal tear 139. The counter junction 120 is positioned at the tear 139, as shown in Figure 95. To anchor the distal legs 124 of the counter-gripping fastener 285, the needle/trocar 103 is partially withdrawn while the compressive sleeve 109 is held stationary, as shown in Figure 96. The distal legs 124 and the gripping elements 113 act as hooks anchoring into the torn portion of the meniscus 135. By pulling the suture 122, the torn portion anchored by the distal legs 124 of the fastener 285 rejoins the main body of the meniscus 135, as shown in Figure 97. With constant tension on the suture 122, the needle 103 then compressive sleeve 109 are withdrawn to anchor the proximal legs 124 within the main body of the meniscus 135 for a tight meniscal 135 repair, as shown in Figure 98. The suture 122 is preferred to be biodegradable and excess suture 122 is cut off.

In summary, the elastic legs 124 of the expandable fastener 144, 284, 285 or 286 are resiliently straightened by the trocars 103 during tissue insertion. The legs 124 are then allowed to curve after the withdrawal of the trocar 103, pressing the gripping elements 113 laterally into the tissue for fastening. In the curved position, the elastic leg 124 can have more than one curvature. Location and degree of the curvature of the legs 124 of the fastener 144, 284, 285 or 286 can vary. Curvatures of the legs 124 can also be asymmetrical or not in mirror image to each other.

The curved position can also be called the predisposed, deployed or relaxed position of the fastener 144, 284, 285 or 286. The straightened position can also be called the

generally parallel, inserting, delivery, or installing position of the fastener 144, 284, 285 or 286.

A wide range of materials can be used to fabricate the expandable fastener 144, 284, 285 or 286. Biocompatible polymers, such as polypropylene, polyethylene, poly-ether-
5 ether-ketone, acetal resin, polysulfone or polycarbonate are possible candidates. For biodegradable capability, the expandable fastener 144, 284, 285 or 286 can be made with polylactate, polyglycolic, poly(lactide-co-glycolide), polycaprolactone, trimethylene carbonate or combinations of these materials. Many of these degradable polymers are US FDA approved products. Other degradable polymers, such as polydioxanone,
10 polyanhydride, trimethylene carbonate, poly-beta-hydroxybutyrate, polyhydroxyvalerate, poly-gama-ethyl-glutamate, poly(DTH iminocarbonate), poly(bisphenol A iminocarbonate), poly-ortho-ester, polycyanoacrylate or polyphosphazene can also be used. For strength, durability and elasticity, nickel-titanium alloy or spring-tempered stainless steel can be used.

15 The expandable fastener 144, 284, 285 or 286 can also be coated with biocompatible polymers, such as polyurethane, polytetrafluoroethylene, silicon, polyethylene or other material. For additional biological and surgical benefits, the expandable fastener 144, 284, 285 or 286 can also be coated with lubricant, growth factor, nutrient, buffering agent, collagen, hydroxyapatite, analgesic, sealant, blood clotting, antibiotic, water repellent,
20 radiopaque or echogenic agents. All materials should be able to withstand sterilization by gamma, electron beam, autoclave, ETO, plasma or UV light to prevent infection.

The trocar/needle 103 and compressive sleeve 109 can be made with stainless steel, titanium, nickel titanium other metal or alloy. The trocar/needle 103 and compressive sleeve 109 can be coated with lubricant, antibiotic, blood clotting, radiopaque or
25 echogenic agents. For hard-to-reach surgical sites, the trocar/needle 103 can be made curved to gain accessibility for the surgeon. To accommodate the curvature of the trocar/needle 103, the compressive sleeve 109 can also be made with elastic material, such as nickel titanium, polypropylene, polyethylene or other flexible material.

The suture 122 can be permanent or biodegradable, braided or monofilament. The
30 suture 122 can also be metallic for strength and durability.

It is to be understood that the present invention is by no means limited to the particular constructions disclosed herein and/or shown in the drawings, but also includes any other modification, changes or equivalents within the scope of the claims. Many features have been listed with particular configurations, curvatures, options, and embodiments. Any one
5 or more of the features described may be added to or combined with any of the other embodiments or other standard devices to create alternate combinations and embodiments.

It should be clear to one skilled in the art that the current embodiments, materials, constructions, methods, tissues or incision sites are not the only uses for which the invention may be used. It has been foreseen that the expandable fastener 144, 284, 285 or
10 286 and the trocar/needle 103 can be applied in other surgical and non-surgical purposes. In fact, the expandable fastener 144, 284, 285 or 286 can be used to fasten pictures on walls or machine parts prone to loosening. Different materials, constructions, methods or designs for the expandable fastener 144, 284, 285 or 286, trocar/needle 103 or the compressive sleeve 109 can be substituted and used. Nothing in the preceding description
15 should be taken to limit the scope of the present invention. The full scope of the invention is to be determined by the appended claims.

What is claimed is:

1. An expandable fastener deployable with a trocar, comprising:

a first leg formed of an elastic material and having a first retainer passage extending through at least a portion thereof, said first leg having a curved position and a resiliently straightened position,

a first plurality of tissue gripping elements located on a concave side of said first leg when said first leg is in said curved position,

a second leg formed of an elastic material and having a second retainer passage extending through at least a portion thereof, said second leg having a curved position and a resiliently straightened position,

a second plurality of tissue gripping elements located on a concave side of said second leg when said second leg is in said curved position,

wherein said first and second retainer passages are sized and configured to retain the trocar.

2. The expandable fastener of claim 1, further comprising a first head portion attached to a proximal end of said first leg and a second head portion attached to a proximal end of said second leg.

3. The expandable fastener of claim 2, wherein said first head portion has at least one alignment opening, and said second head portion has at least one alignment peg that extends into said at least one alignment opening.

4. The expandable fastener of claim 1, further comprising a first groove in said first leg and a second groove in said second leg, said first retainer passage enclosing a portion of said first groove and said second retainer passage enclosing a portion of said second groove.

5. The expandable fastener of claim 1, wherein

said first and second legs are connected by a bridge,

said first retainer passage extends from a proximal end to a distal end of said first leg,
and said second retainer passage extends from a proximal end to a distal end of said second leg.

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6. The expandable fastener of claim 1, wherein the trocar is located in said first and second retainer passages, thereby holding said first and second legs in said resiliently straightened positions.

10

7. The expandable fastener of claim 2, further comprising a retainer ring sized and configured to fit around both of said first and second legs.

8. An expandable fastener, comprising:

15

a first elastically curved section having a first head portion, a first leg portion extending from said first head portion, a first groove indenting along a length of said first head portion and said first leg portion, and a first passage covering a portion of said first groove,

20

a second elastically curved section having a second head portion, a second leg portion extending from said second head portion, a second groove indenting along a length of said second head portion and said second leg portion, and a second passage covering a portion of said second groove,
and a retainer ring sized and configured to fit around said first and second elastically curved sections.

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9. The expandable fastener of claim 8, further comprising a plurality of tissue gripping elements extending from an outside surface of said first and second elastically curved sections.

30

10. The expandable fastener of claim 9, wherein said plurality of tissue gripping elements form rings around said expandable fastener along said outside surface.

11. The expandable fastener of claim 9, wherein said plurality of tissue gripping elements form threading along said outside surface.
- 5 12. The expandable fastener of claim 11, wherein said threading is configured as a self-tapping screw thread.
13. The expandable fastener of claim 11, wherein said tissue gripping elements are angled.
- 10 14. The expandable fastener of claim 9, wherein said tissue gripping elements are barbs.
15. The expandable fastener of claim 14, wherein said tissue gripping elements are pointed in more than one direction.
- 15 16. The expandable fastener of claim 9, wherein said tissue gripping elements are semi-circular ridges that extend from said outside surface of said first and second elastically curved sections.
17. The expandable fastener of claim 8, further comprising a needle, said needle sized and
20 configured to fit into said first and second grooves and said first and second passages.
18. The expandable fastener of claim 8, wherein said first and second elastically curved sections may be resiliently straightened such that said first groove aligns with said second groove and a deployment needle may be located through said first and second grooves and
25 said first and second passages, thereby holding said first and second elastically curved sections in straightened positions.
19. The expandable fastener of claim 8, wherein:
a first distance is between a proximal end of said first and second curved sections,
30 a second distance is between a distal end of said first and second curved sections,

and wherein a curvature of said first curved section is configured such that said second distance is larger than said first distance.

20. The expandable fastener of claim 19, wherein a curvature of said second curved
5 section is configured such that said second distance is larger than said first distance.
- 21: The expandable fastener of claim 1 or 8, further comprising a suture attached to said expandable fastener.
- 10 22. The expandable fastener of claim 8, wherein said first elastically curved section has a third groove indenting along said first leg portion and said second elastically-curved section has a mating tongue extending from said second leg portion.
23. The expandable fastener of claim 4 or 8, wherein said first and second grooves are non
15 semi-cylindrical.
24. The expandable fastener of claim 1 or 8, wherein said passages are cylindrical.
25. The expandable fastener of claim 1 or 8, wherein said first and second passages are D-
20 shaped.
26. The expandable fastener of claim 8, wherein said first and second grooves extend to
an opening in a tip of said first and second elastically curved sections such that a needle
may extend out from said tip.
25
27. The expandable fastener of claim 1 or 8, wherein said first and second legs are tapered.
28. The expandable fastener of claim 7 or 8, wherein said retainer ring is tapered.
30

29. The expandable fastener of claim 1 or 8, wherein said expandable fastener is formed of modular components.
30. The expandable fastener of claim 1 or 8, wherein said expandable fastener is formed of one or more materials chosen from the group of materials consisting of biocompatible polymers, polypropylene, polyethylene, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate, biodegradable materials, polylactate, polyglycolic, poly-lactide-co-glycolide, polycaprolactone, trimethylene carbonate, polydioxanone, polyanhydride, trimethylene carbonate, poly-beta-hydroxybutyrate, polyhydroxyvalerate, poly-gama-ethyl-glutamate, poly-DTH iminocarbonate, poly-bisphenol A iminocarbonate, poly-ortho-ester, polycyanoacrylate and polyphosphazene.
31. The expandable fastener of claim 1 or 8, wherein said expandable fastener is formed of a material chosen from the group of materials consisting of nickel-titanium alloy and spring-tempered stainless steel.
32. The expandable fastener of claim 1 or 8, further comprising a coating on an exterior surface of said expandable fastener.
33. The expandable fastener of claim 32, wherein said coating is chosen from the group of coatings consisting of biocompatible polymers, polyurethane, polytetrafluoroethylene, silicon, polyethylene, lubricant, growth factor, nutrient, buffering agent, collagen, hydroxyapatite, analgesic agent, sealant, blood clotting agent, antibiotic agent, water repellent agent, radiopaque agent and echogenic agent.
34. The expandable fastener of claim 2 or 8, wherein said first and second head portions have tissue gripping elements extending therefrom.
35. The expandable fastener of claim 2 or 8, wherein said first and second head portions form an opening for a screw driver.

36. The expandable fastener of claim 2 or 8, wherein said first and second head portions form a bolt-head shape.
- 5 37. The expandable fastener of claim 2 or 8, wherein said first and second head portions further comprise at least one tissue ingrowth opening.
38. The expandable fastener of claim 1 or 8, wherein a tissue-contacting surface located proximate said first and second legs is smooth.
- 10 39. The expandable fastener of claim 8, wherein said first and second grooves extend through said first and second head portions.
40. The expandable fastener of claim 2 or 8, wherein said first and second head portions
15 have threading and further comprising a nut sized and configured to rotate about said threading.
41. The expandable fastener of claim 8 further comprising a third elastically curved section extending from said first head portion and a fourth elastically curved section
20 extending from said second head portion.
42. The expandable fastener of claim 41, wherein said third and fourth elastically curved sections further comprising plurality of tissue gripping elements.
- 25 43. The expandable fastener of claim 8, wherein said retainer ring is located around said first and second curved sections.
44. The expandable fastener of claim 8, wherein said retainer ring is located around said
30 first and second head portions.

45. The expandable fastener of claim 8, further comprising at least one alignment opening located in said first curved section, and at least one alignment peg extending from said second curved section, said at least one alignment peg sized and configured to fit within said at least one alignment opening.

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46. The expandable fastener of claim 45, wherein said at least one alignment opening is located in said first head portion and said at least one alignment peg extends from said second head portion.

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47. An expandable fastener, comprising:

a first elastically curved section having a first head portion, a first leg portion extending from said first head portion, at least one groove indenting along a length of said first head portion and said first leg portion,

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a second elastically curved section having a second head portion, a second leg portion extending from said second head portion, at least one tongue extending along a length of said second head portion and said second leg portion, wherein said at least one tongue is sized and configured to fit in said at least one groove,

and a retainer ring sized and configured to fit around said first and second elastically curved sections.

20

48. The expandable fastener of claim 47, wherein said first and second elastically curved sections are held together with a water degradable adhesive.

25

49. The expandable fastener of claim 47, wherein said first and second elastically curved sections are held together with a water degradable band.

50. An expandable fastener for deployment with a needle, said expandable fastener comprising:

a first leg having tissue gripping elements located on a concave surface thereof, said
first leg having a first curved position and a second resiliently straightened
position,
a second leg having tissue gripping elements located on a concave surface thereof,
5 said second leg having a first curved position and a second resiliently
straightened position,
a head portion located at an end of said first and second legs,
at least one passage extending through at least one of said first and second legs, said
at least one passage sized and configured to allow the needle to be located
10 therein,
wherein, when the needle is located within said at least one passage, at least one of
said first and second legs is held in said resiliently straightened position.

51. The expandable fastener of claim 50, wherein said expandable fastener is deployed
15 with a device having two needles, wherein said passage extends through said first leg, said
expandable fastener further comprising a second passage extending through said second
leg, said head portion connecting a proximal end of said first leg and a proximal end of
said second leg.

20 52. The expandable fastener of claim 51, wherein each of said passages has an opening
with a D-shaped cross section.

53. The expandable fastener of claim 52, wherein said first and second curved positions
are configured such that said first and second legs curve apart and rounded edges of said
25 D-shaped cross sections are located toward convex sides of curvatures of said first and
second legs.

54. The expandable fastener of claim 52, wherein said first and second curved positions
are configured such that said first and second legs curve together and rounded edges of

said D-shaped cross sections are located toward convex sides of curvatures of said first and second legs.

55. The expandable fastener of claim 50, further comprising a retainer ring located around
5 said first and second legs proximate said head portion.

56. The expandable fastener of claim 55, wherein said retainer ring is tapered.

57. The expandable fastener of claim 50, wherein said passage forms a portion of a first
10 groove extending the length of said first leg, said expandable fastener further comprising a second passage forming a portion of a second groove extending the length of said second leg, and wherein, when the needle is located within said first and second passages, said first and second legs are held together in said straightened positions.

58. The expandable fastener of claim 57, wherein said first groove has a first recess sized
15 and configured to receive said second passage and wherein said second groove has a second recess sized and configured to receive said passage forming said portion of said first groove.

59. The expandable fastener of claim 57, wherein, when said first and second legs are in
20 said straightened positions, the tissue gripping elements located on said first and second legs form rings around said legs.

60. The expandable fastener of claim 59, wherein said tissue gripping elements are angled,
25 such that when said first and second legs are in said resiliently straightened positions, said tissue gripping elements simulate threading along an outer surface of said first and second legs.

61. The expandable fastener of claim 60, wherein said threading is configured as a self-
30 tapping screw thread.

62. The expandable fastener of claim 50, further comprising a suture attached to said expandable fastener.
- 5 63. The expandable fastener of claim 50, wherein said first leg has a groove indenting along a length thereof and said second leg has a mating tongue extending therefrom.
64. The expandable fastener of claim 50, further comprising at least one alignment opening indenting into said first leg and at least one alignment peg extending from said
10 second leg.
65. The expandable fastener of claim 64, wherein said at least one alignment opening is a groove, and said at least one alignment peg is a tongue that extends into said groove.
- 15 66. The expandable fastener of claim 50, wherein said at least one passage is a non-cylindrical shape.
67. The expandable fastener of claim 50, wherein said at least one passage is cylindrical.
- 20 68. The expandable fastener of claim 50, wherein said at least one passage extends to an opening in a tip of said at least one of said first and second legs such that the needle may extend out from said tip.
69. The expandable fastener of claim 50, wherein said first and second legs are tapered.
25
70. The expandable fastener of claim 50, wherein said tissue gripping elements are barbs.
71. The expandable fastener of claim 70, wherein said tissue gripping elements are pointed in more than one direction.
30

72. The expandable fastener of claim 50, wherein said expandable fastener is formed of modular components.

73. The expandable fastener of claim 50, wherein said fastener is formed of one or more
5 materials chosen from the group of materials consisting of biocompatible polymers, polypropylene, polyethylene, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate, biodegradable materials, polylactate, polyglycolic, poly-lactide-co-glycolide, polycaprolactone, trimethylene carbonate, polydioxanone, polyanhydride, trimethylene carbonate, poly-beta-hydroxybutyrate, polyhydroxyvalerate, poly-gama-ethyl-glutamate, poly-DTH iminocarbonate, poly-bisphenol A iminocarbonate, poly-ortho-
10 ester, polycyanoacrylate and polyphosphazene.

74. The expandable fastener of claim 50, wherein said fastener is formed of a material chosen from the group of materials consisting of nickel-titanium alloy and spring-tempered
15 stainless steel.

75. The expandable fastener of claim 50, further comprising a coating on an exterior surface of said expandable fastener.

20 76. The expandable fastener of claim 75, wherein said coating is chosen from the group of coatings consisting of biocompatible polymers, polyurethane, polytetrafluoroethylene, silicon, polyethylene, lubricant, growth factor, nutrient, buffering agent, collagen, hydroxyapatite, analgesic agent, sealant, blood clotting agent, antibiotic agent, water repellent agent, radiopaque agent and echogenic agent.

25 77. The expandable fastener of claim 50, wherein said head portion has tissue gripping elements extending therefrom.

78. The expandable fastener of claim 50, wherein said head portion forms an opening for
30 a screw driver.

79. The expandable fastener of claim 50, wherein said head portion forms a bolt head shape.

5 80. The expandable fastener of claim 50, wherein said head portion further comprises at least one tissue ingrowth opening.

81. The expandable fastener of claim 50, wherein a tissue-contacting surface located proximate said first and second legs is smooth.

10

82. The expandable fastener of claim 50, wherein said at least one passage opens through said head portion.

83. The expandable fastener of claim 50, wherein said head portion has threading and
15 further comprising a nut sized and configured to rotate about said threading.

84. A method of deploying an expandable fastener with a needle, the method comprising the steps of:

- a) puncturing the tissue with the needle;
- 20 b) pressing on a head of the expandable fastener to slide along the outside of the needle, thereby delivering elastic legs of the expandable fastener into the tissue;
- c) withdrawing the needle;
- d) and allowing the elastic legs to curve, thereby pressing tissue gripping elements into the tissue and anchoring the expandable fastener within the tissue.

25

85. The method of claim 84, wherein said method is used to fasten tissue.

86. The method of claim 84, wherein said method is used to reattach a torn ligament.

30 87. The method of claim 84, further comprising the step of:

- e) using a sleeve to hold the expandable fastener in the tissue while the needle is being withdrawn.

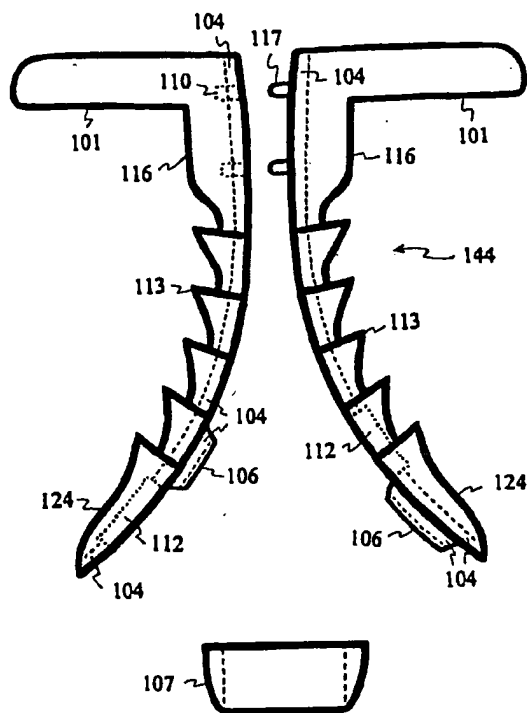


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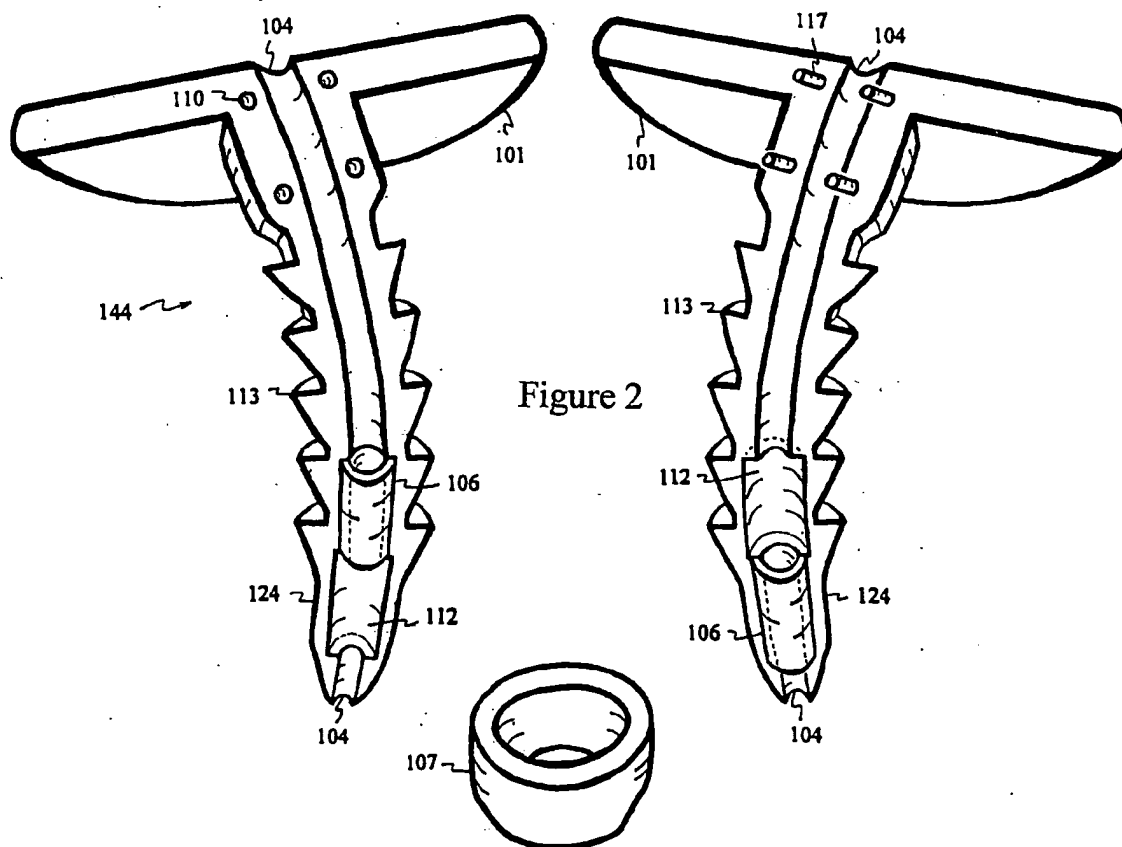


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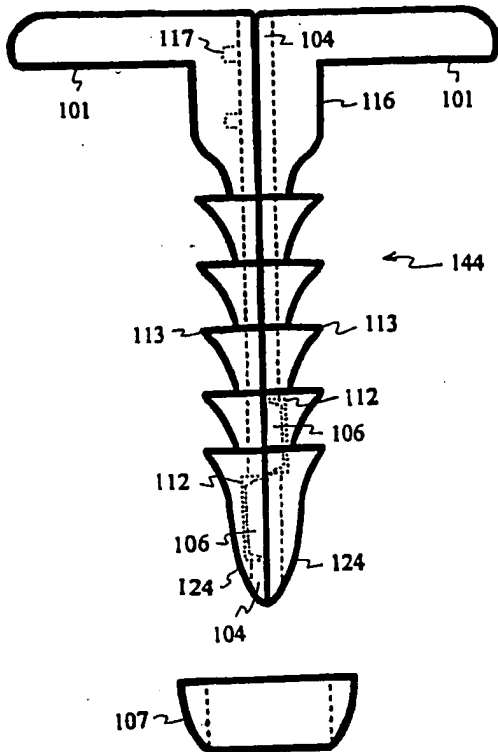


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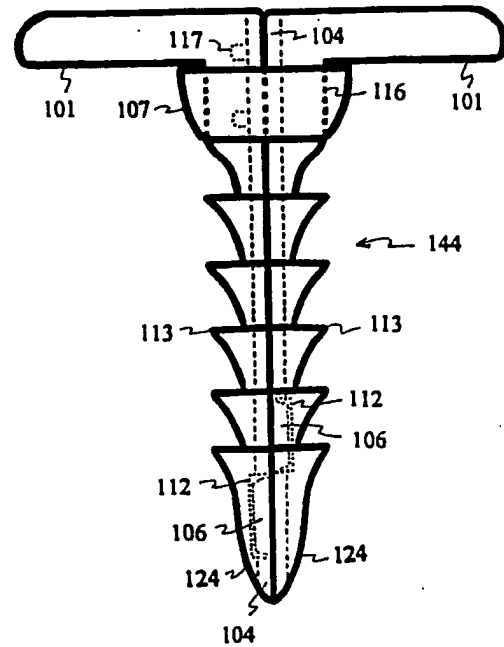
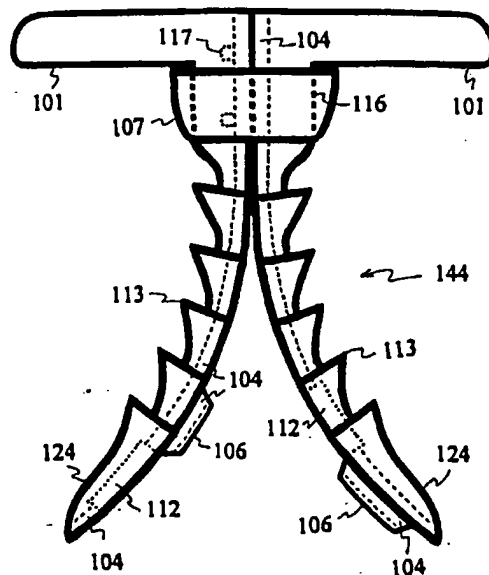


Figure 4

Figure 5



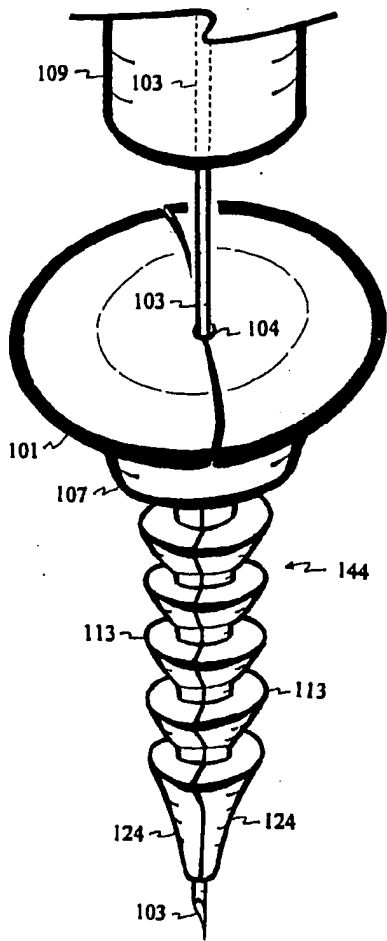


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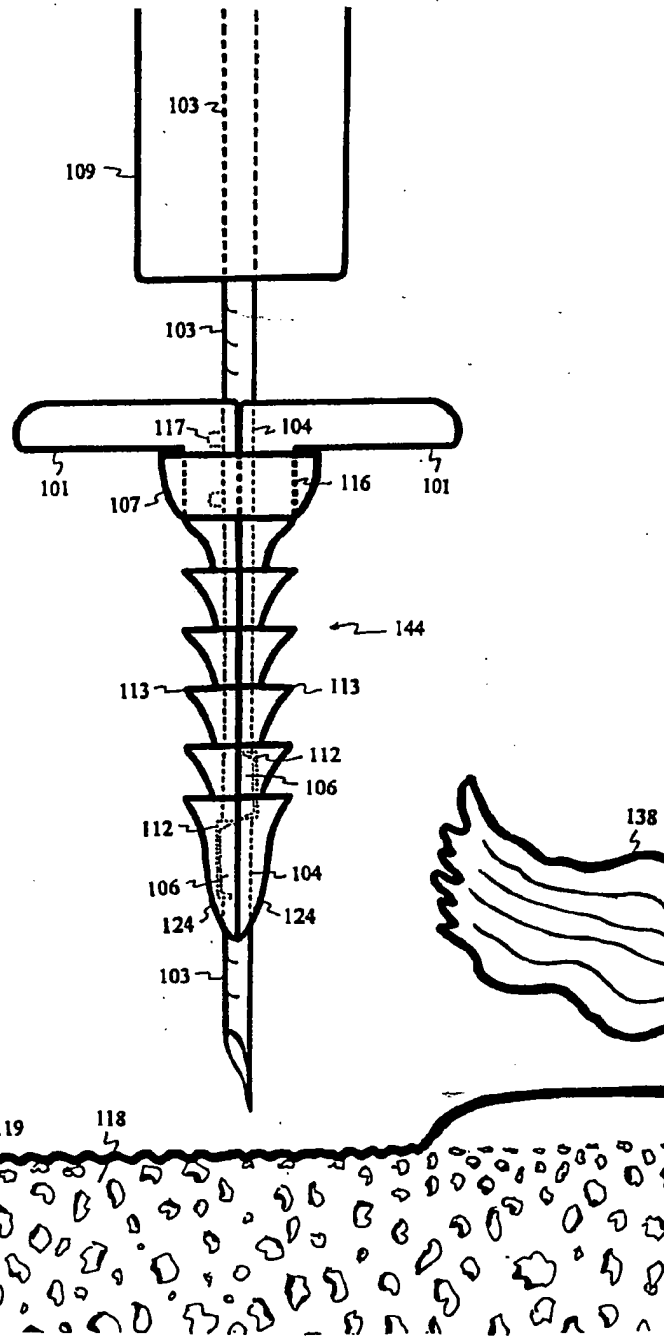
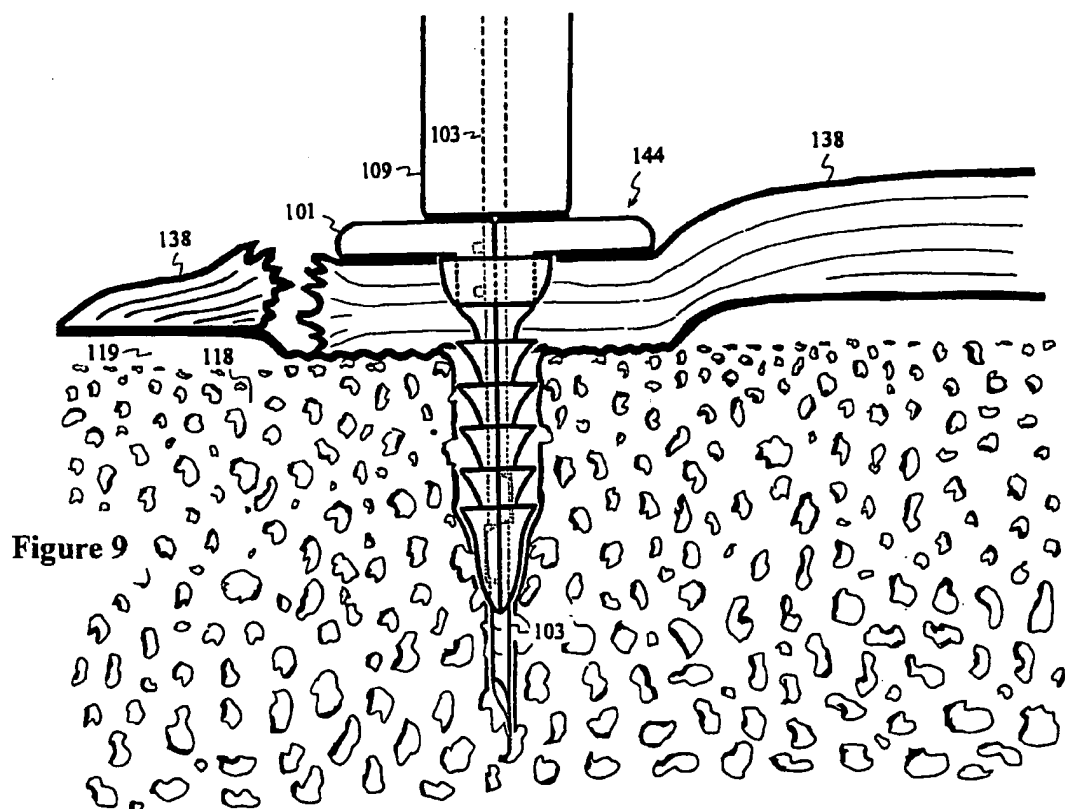
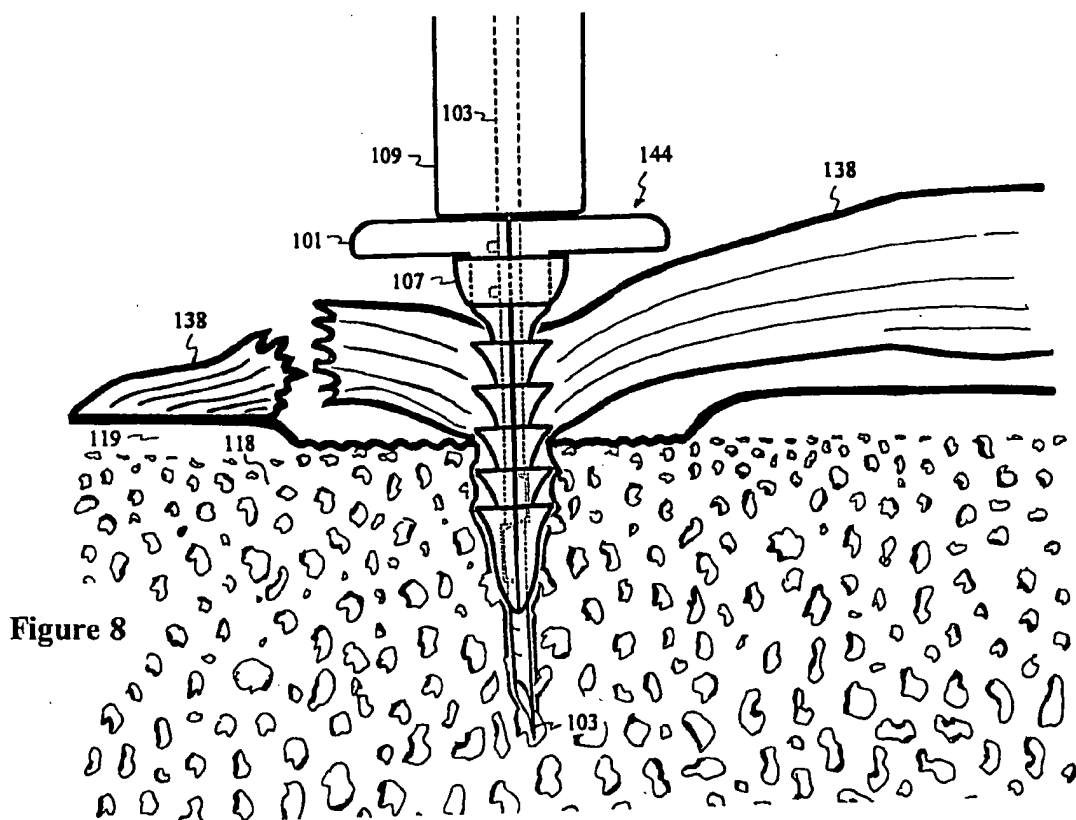


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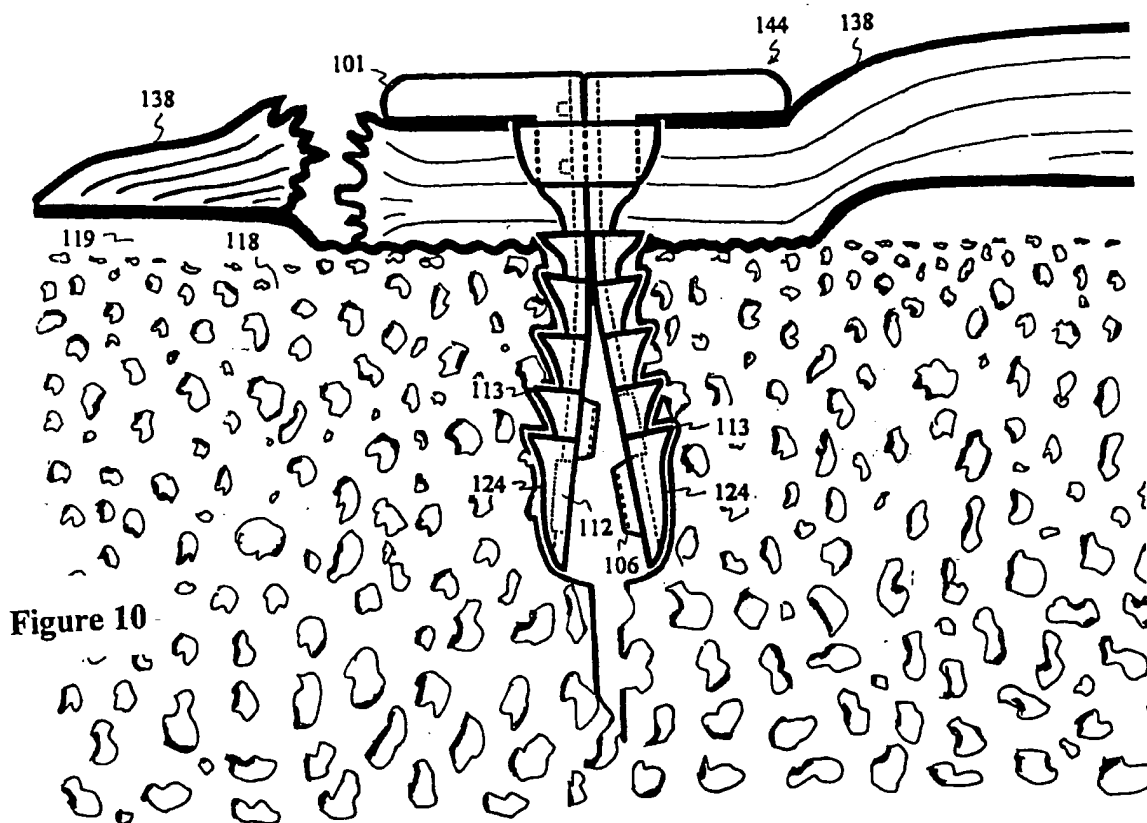
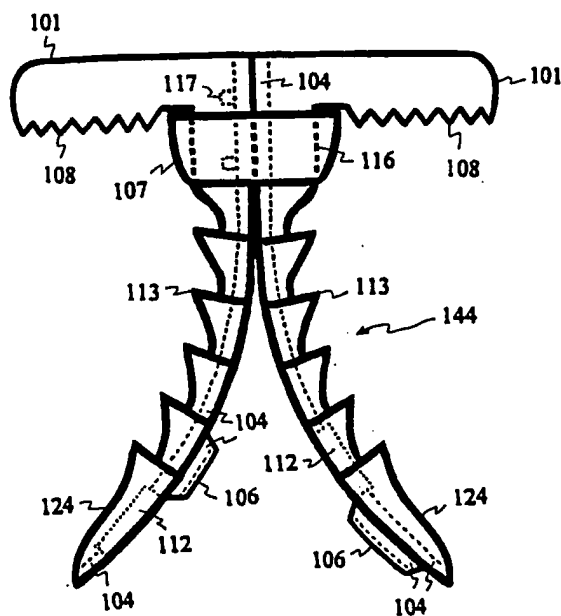
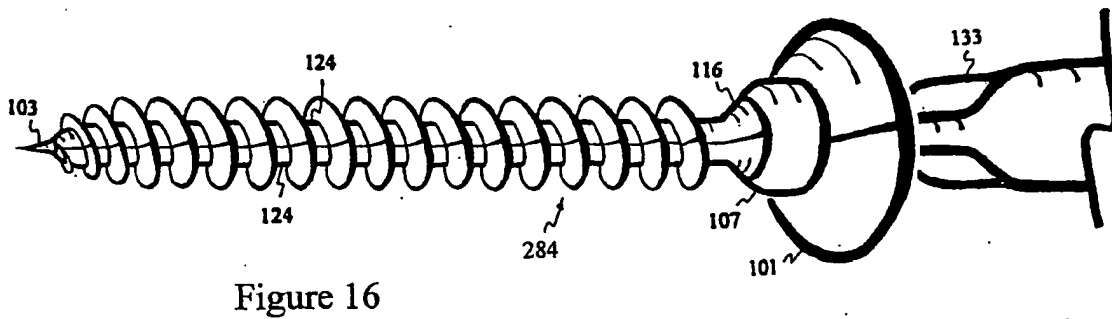
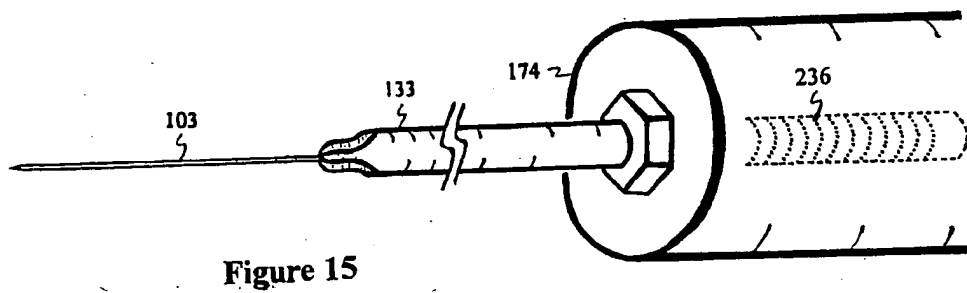
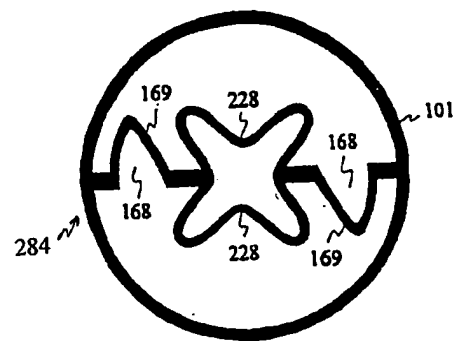
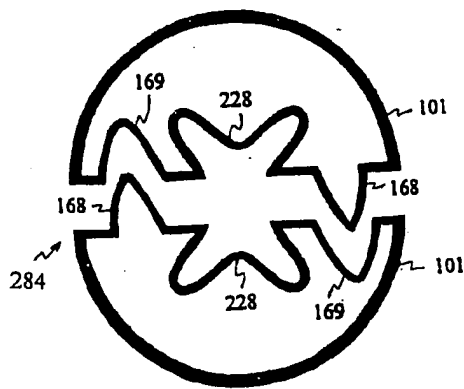
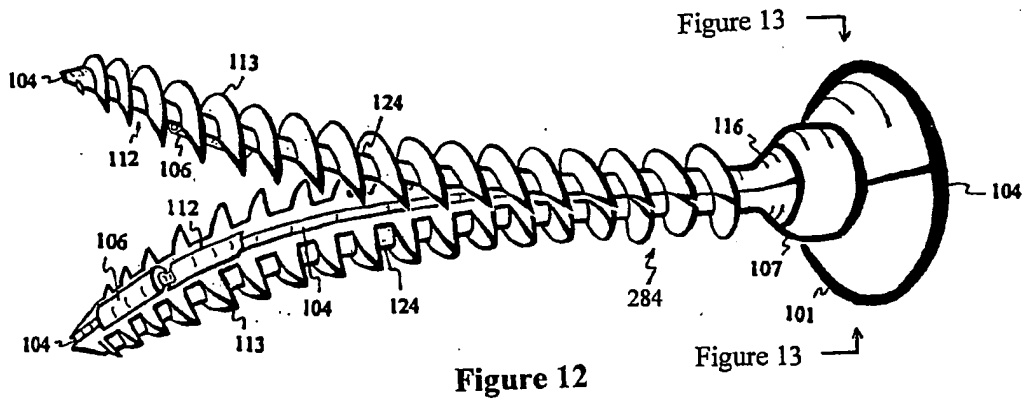


Figure 11





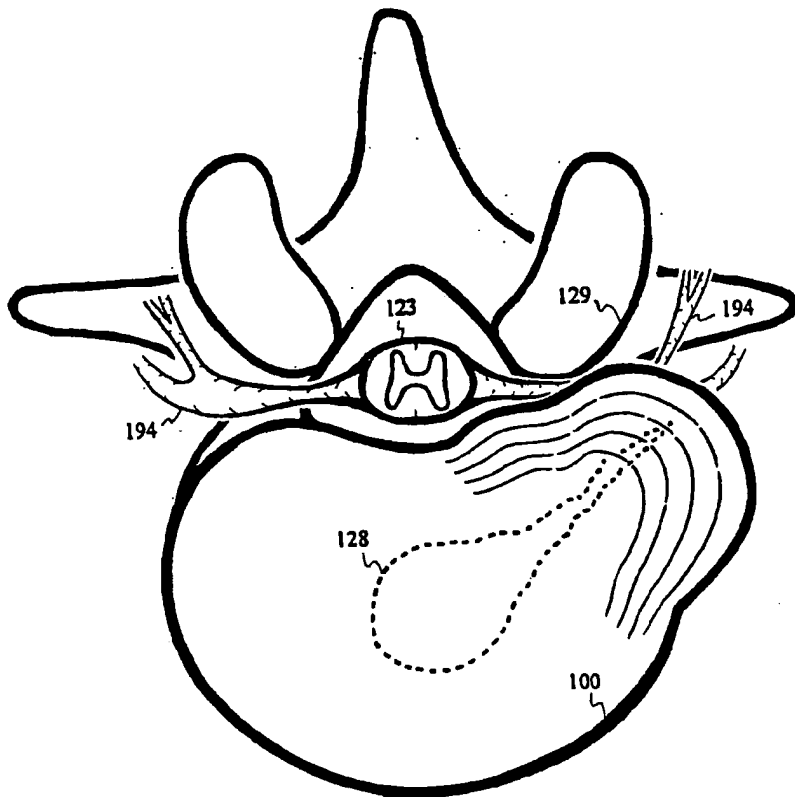


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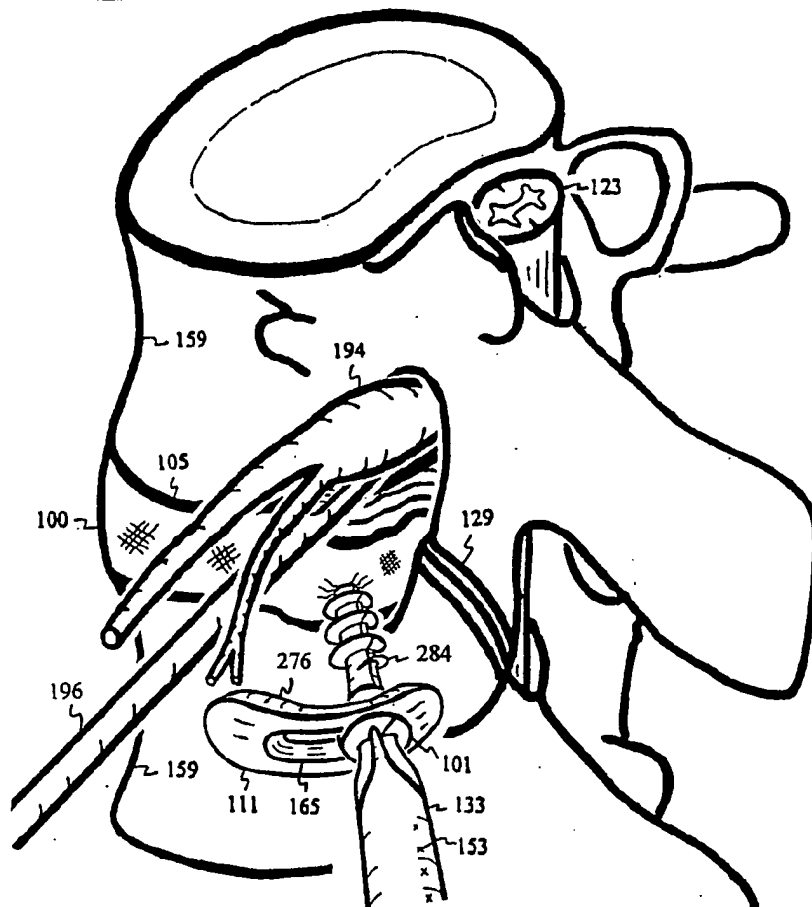


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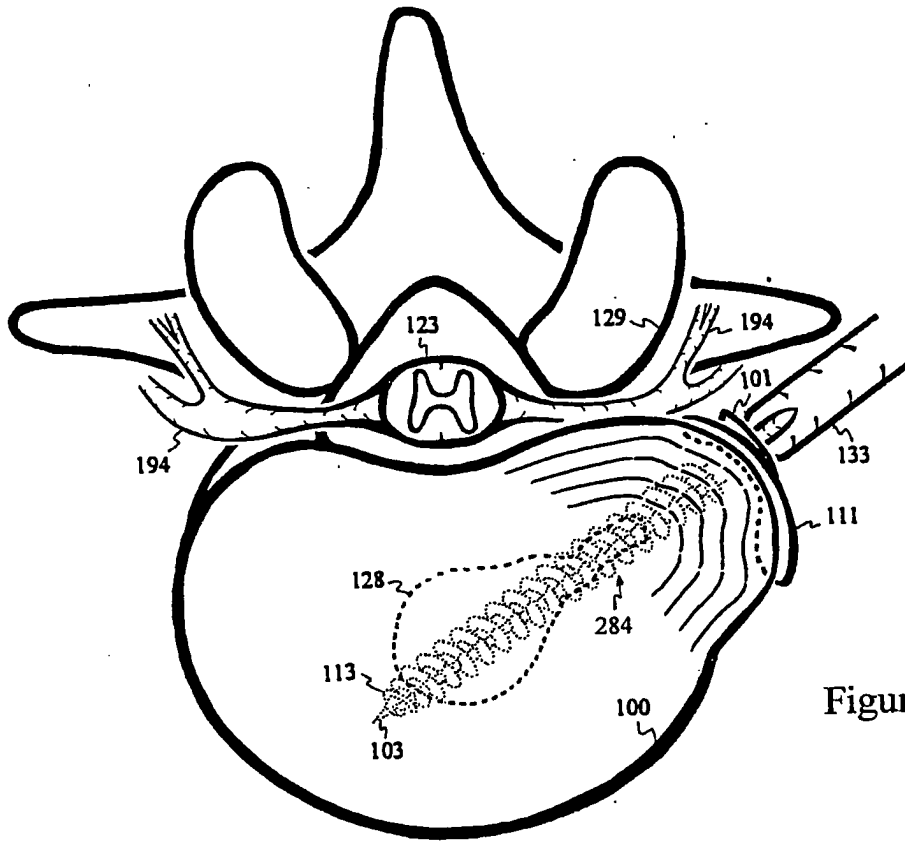


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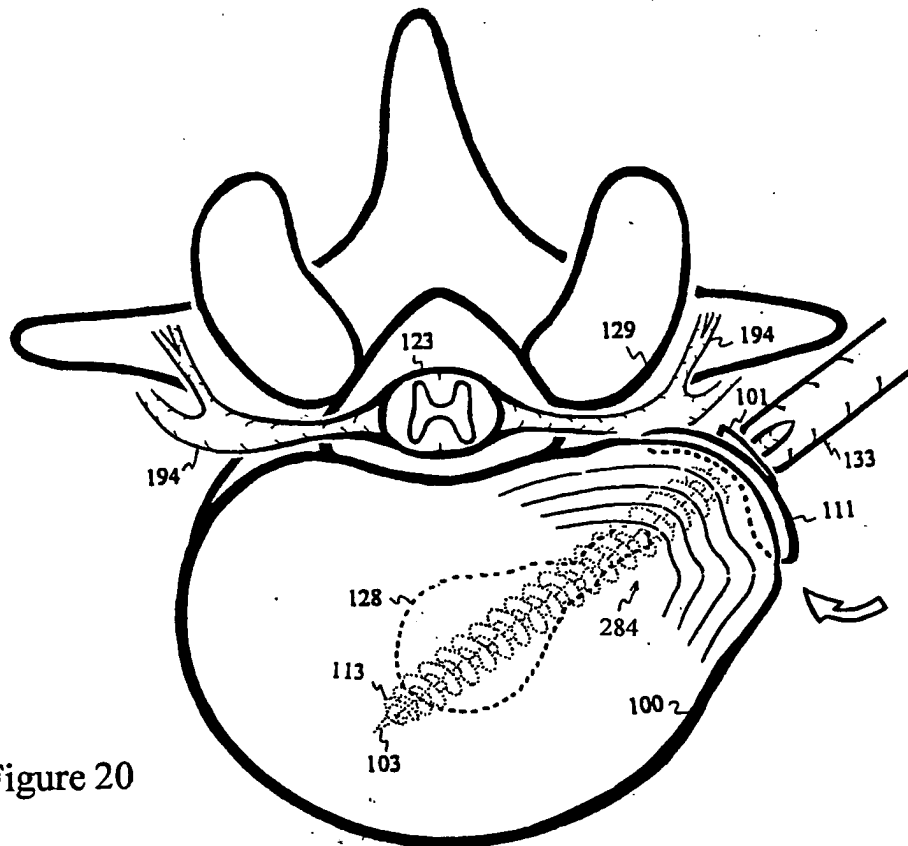
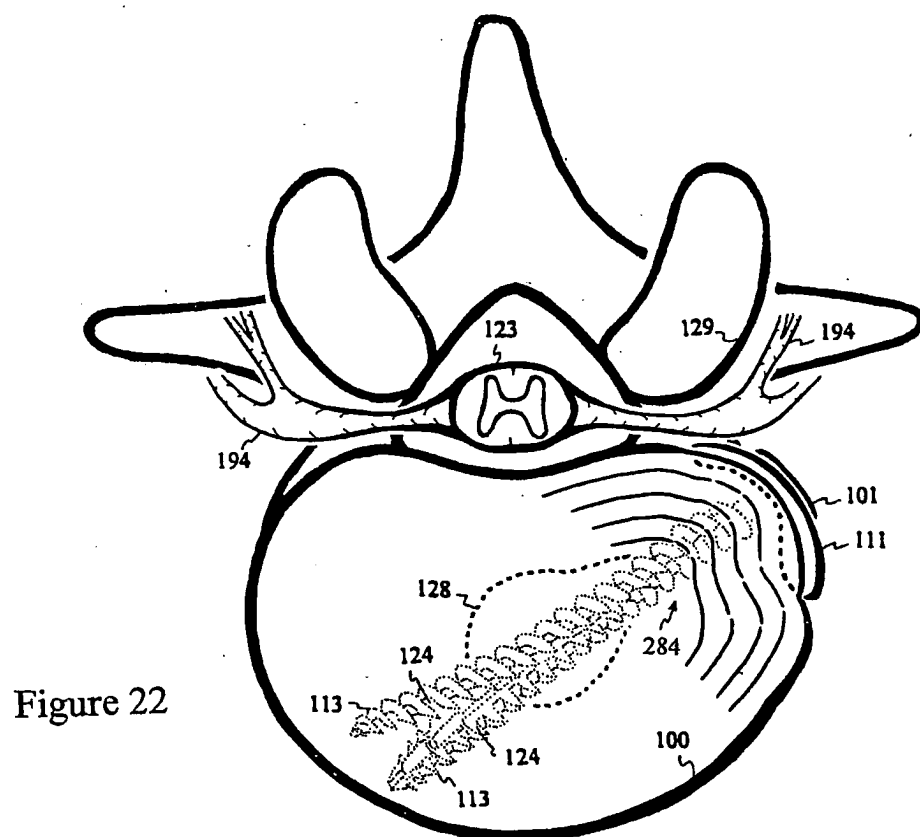
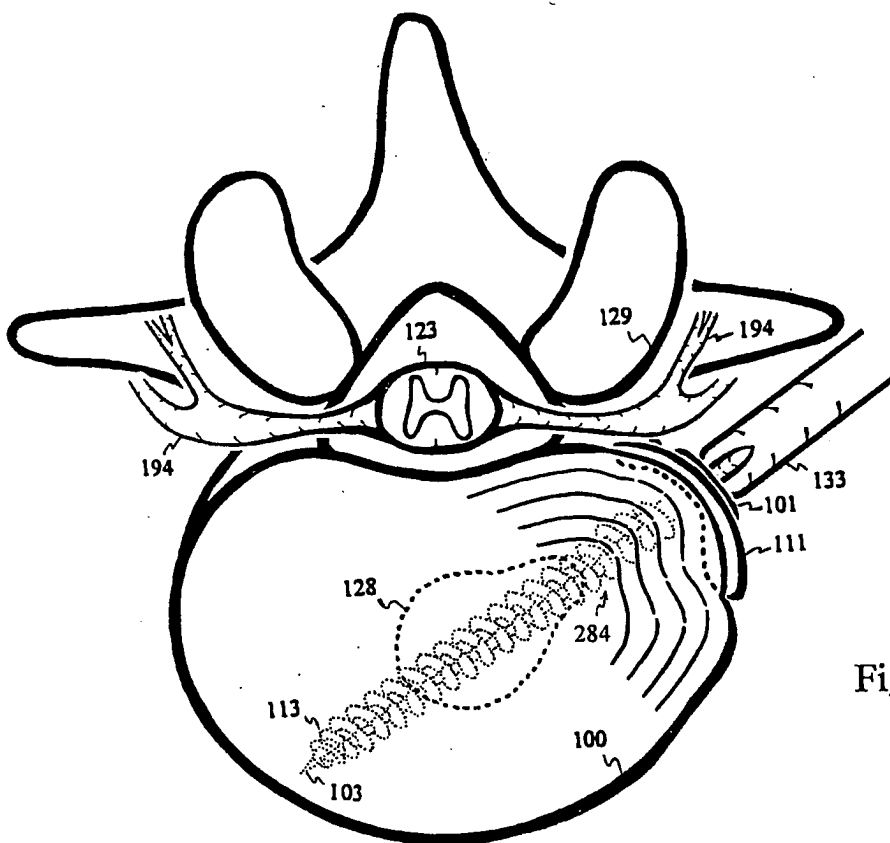


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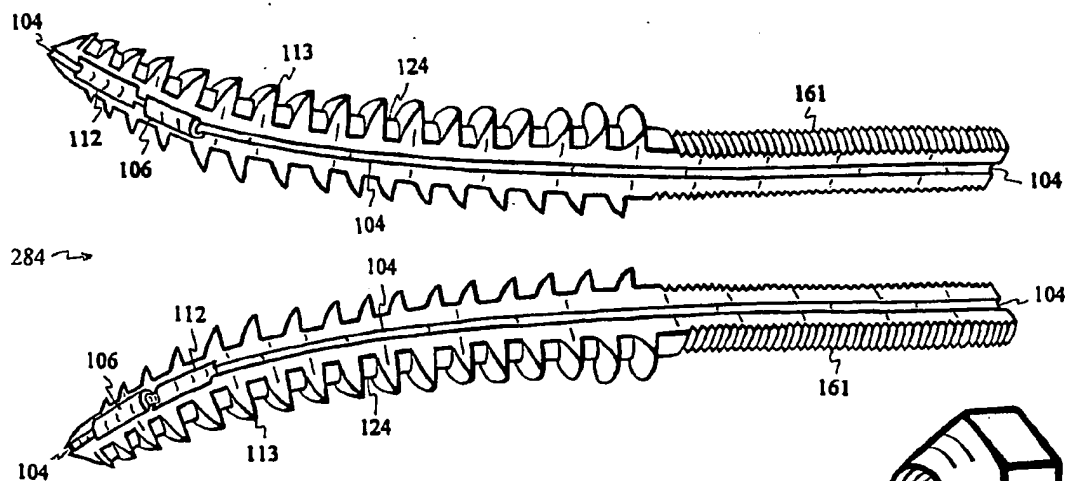


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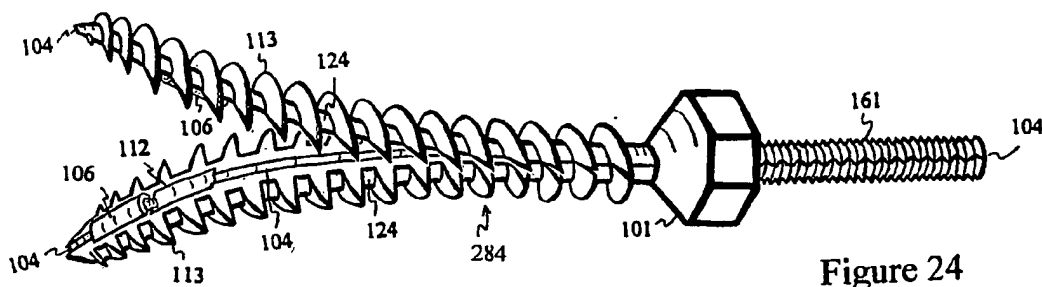
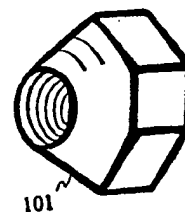


Figure 24

Figure 25

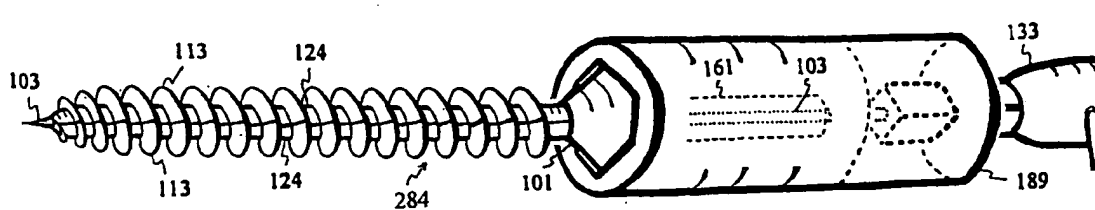
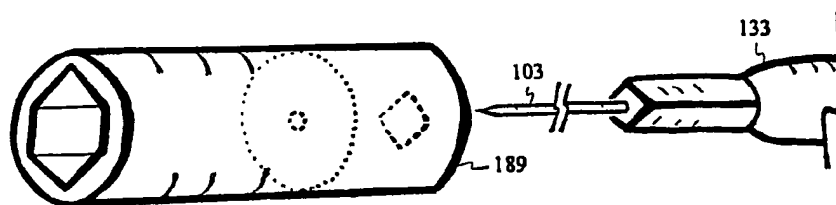


Figure 26

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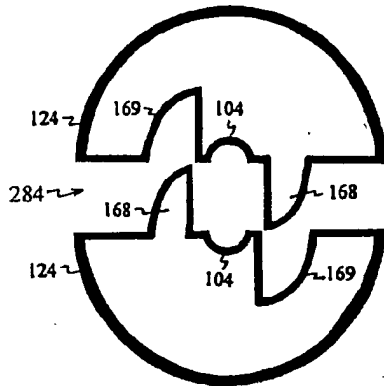
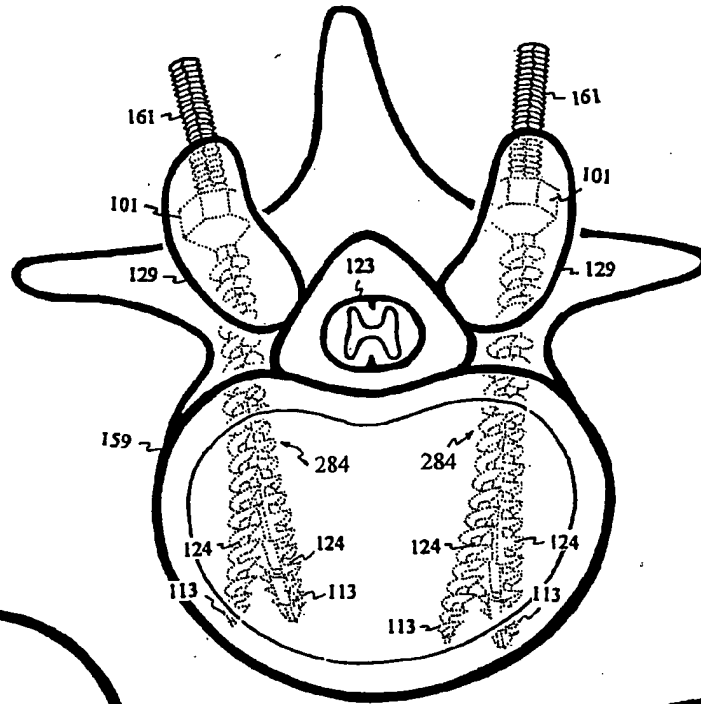


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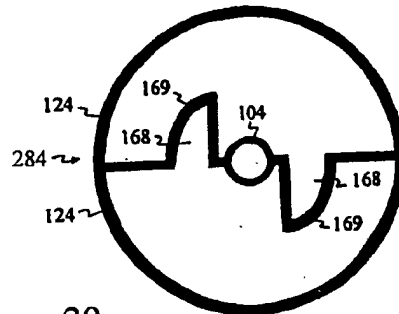


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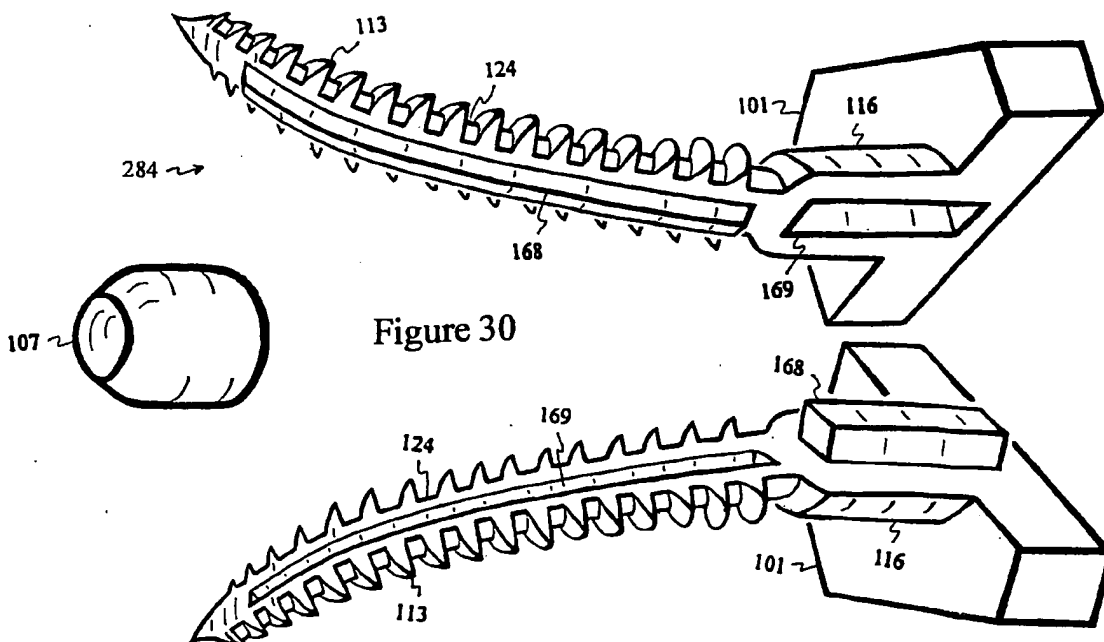


Figure 30

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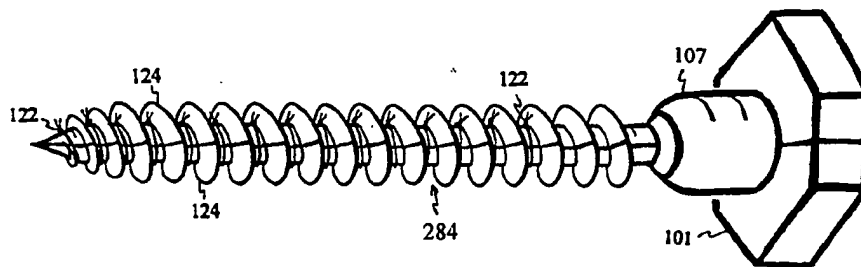
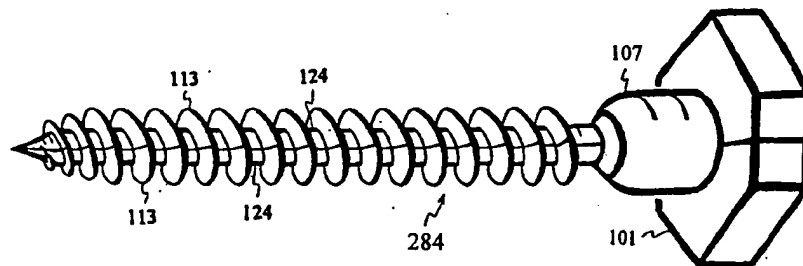


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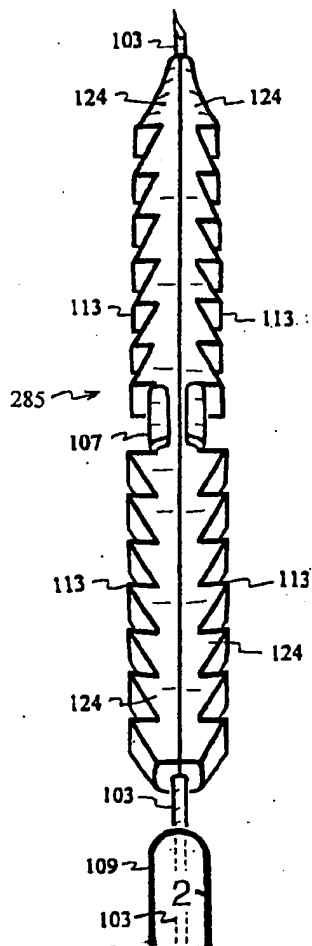


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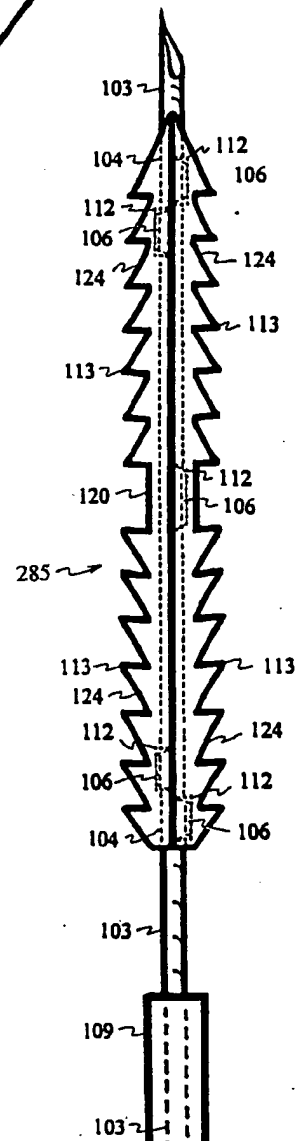


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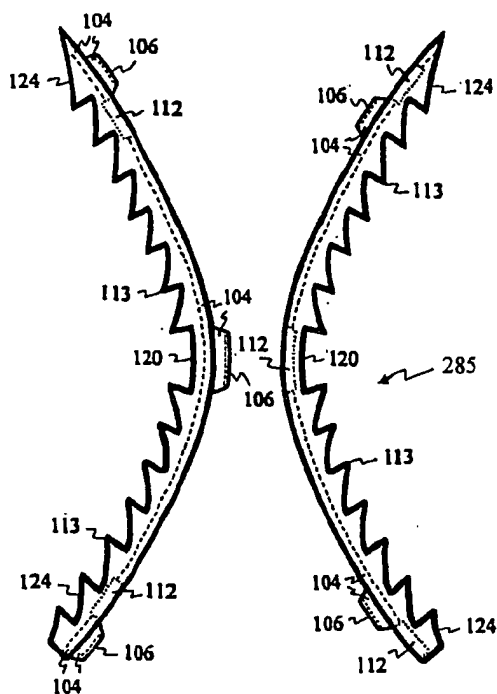


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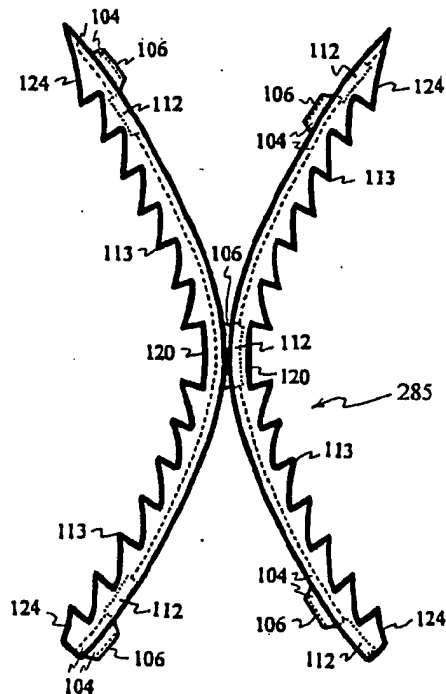


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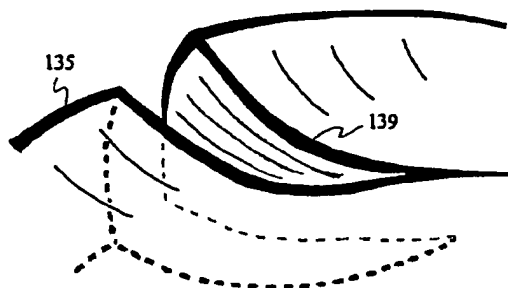
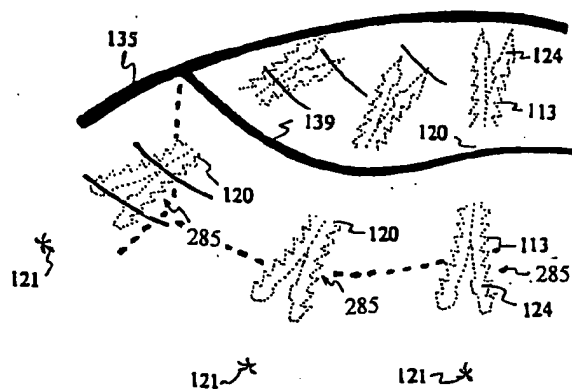


Figure 37

Figure 38



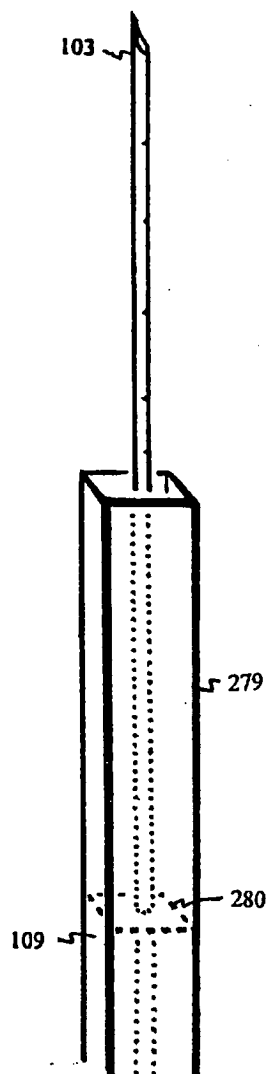


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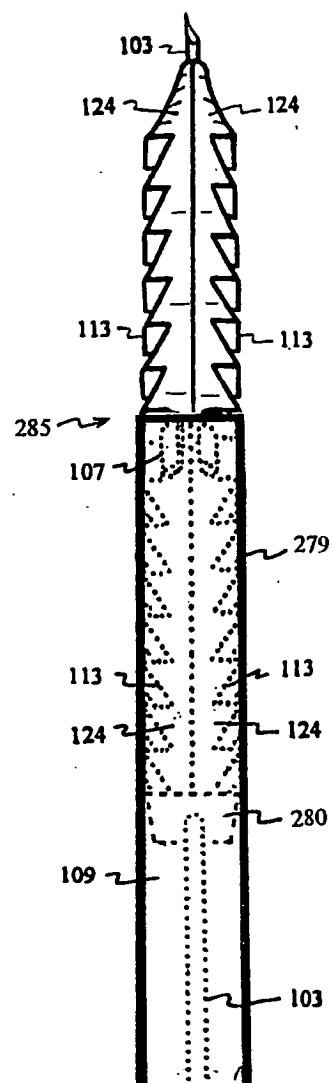


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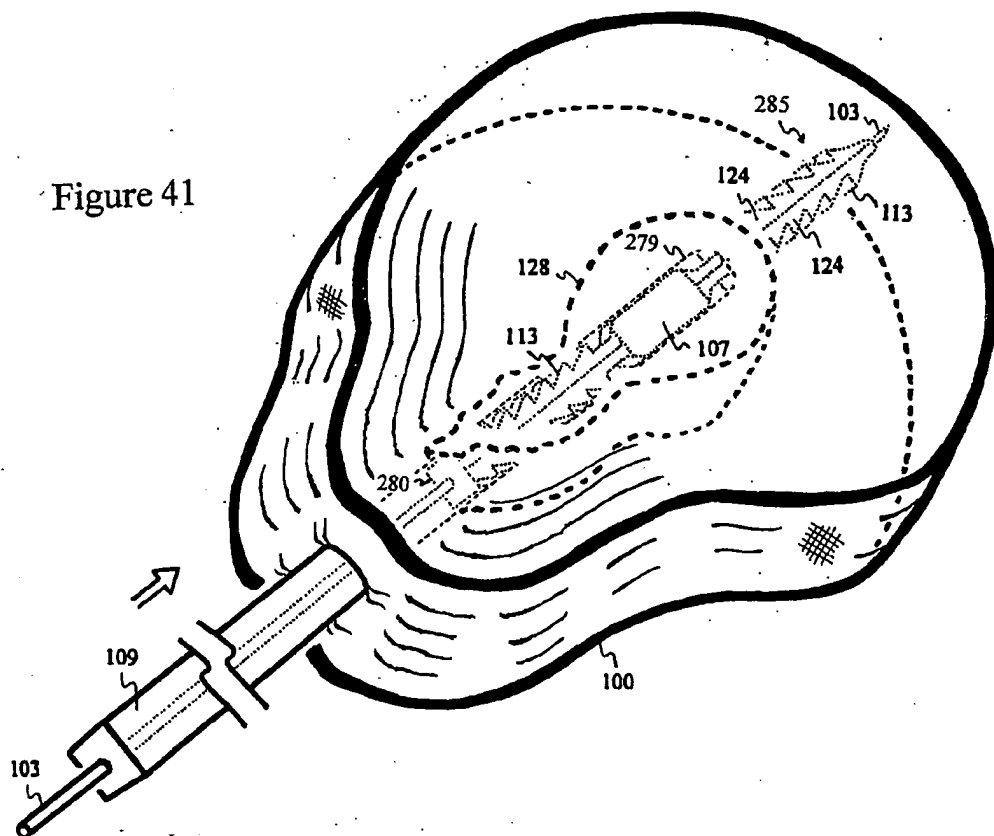


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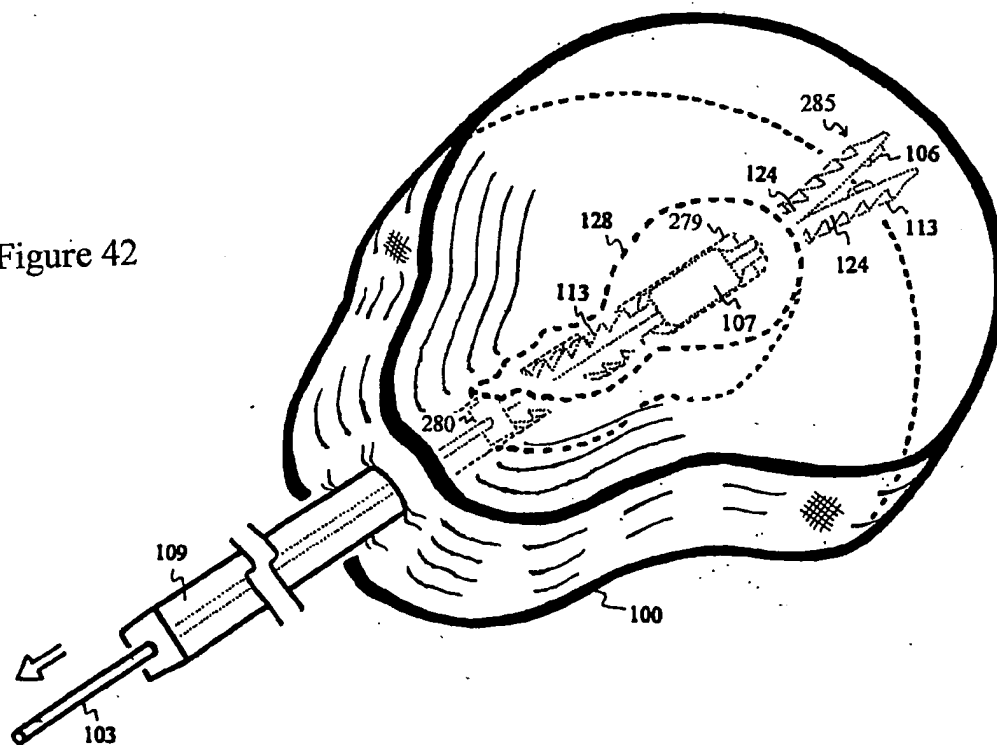


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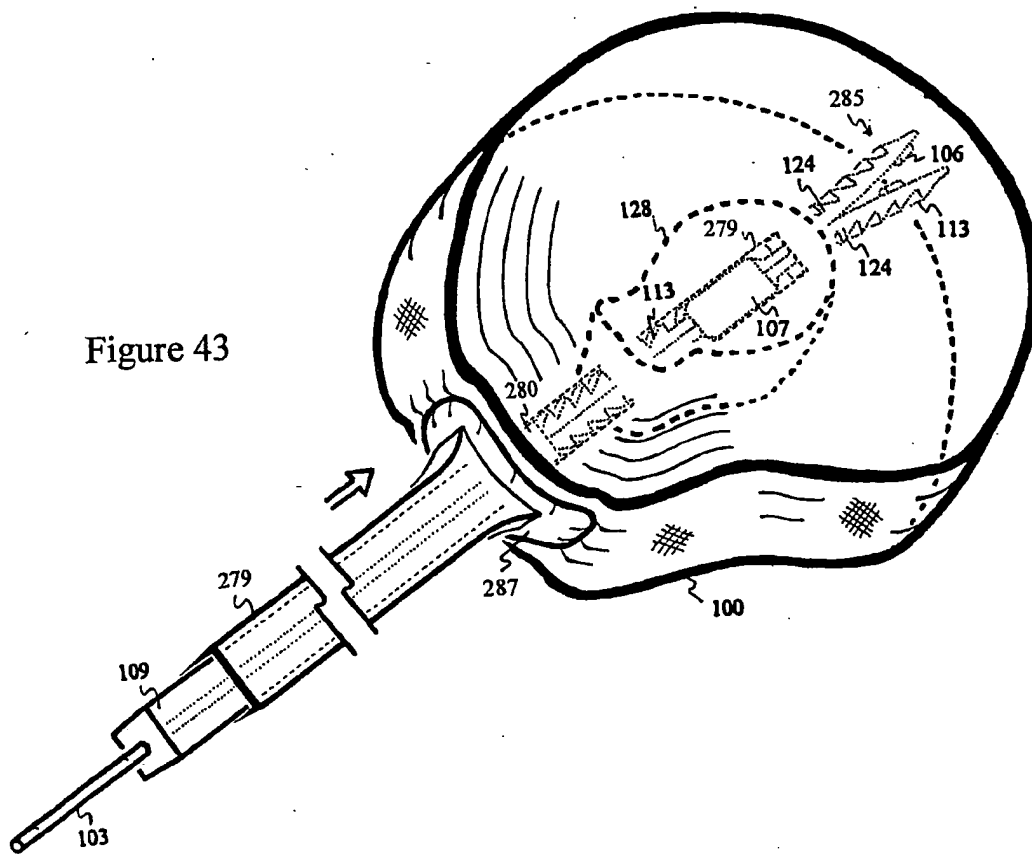
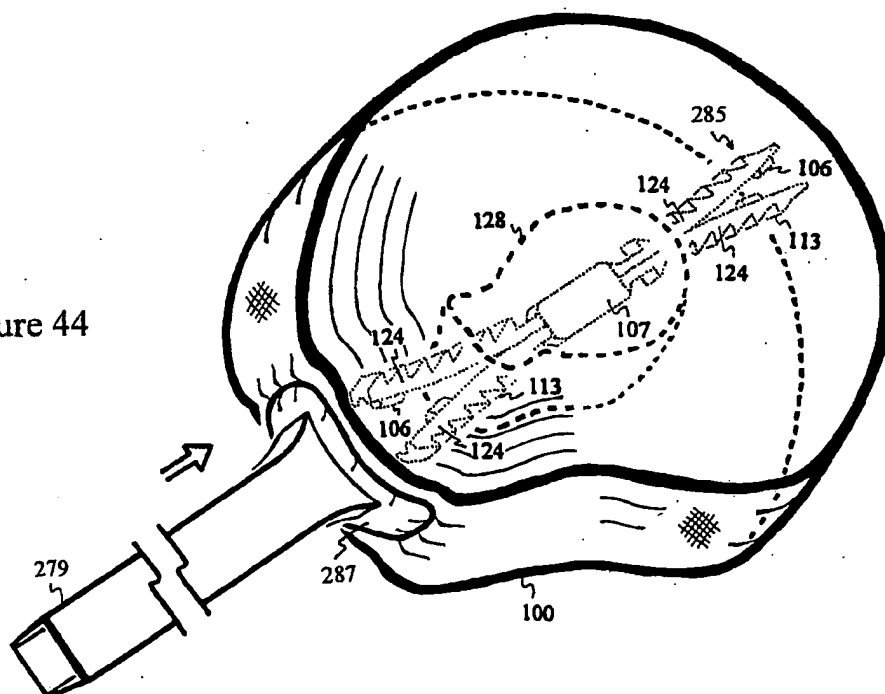


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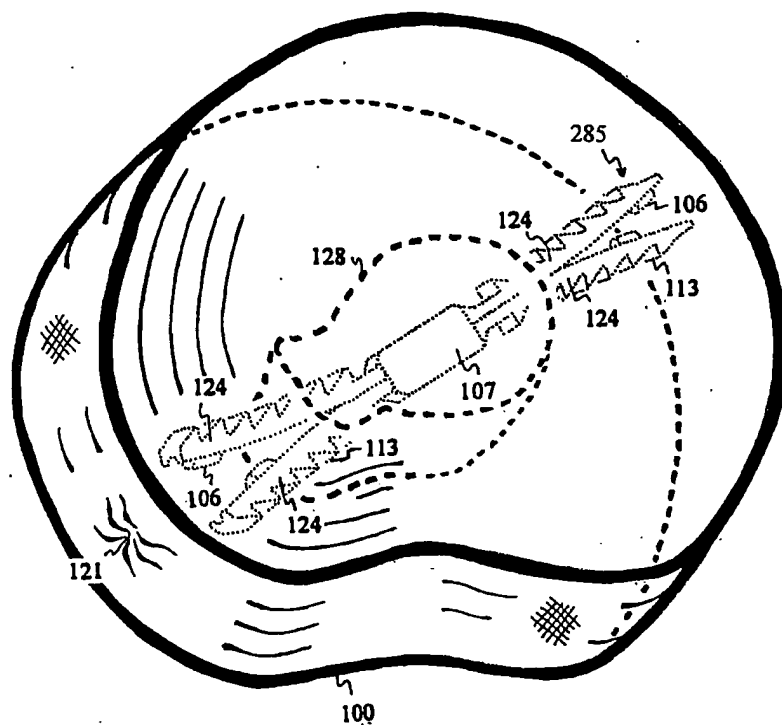


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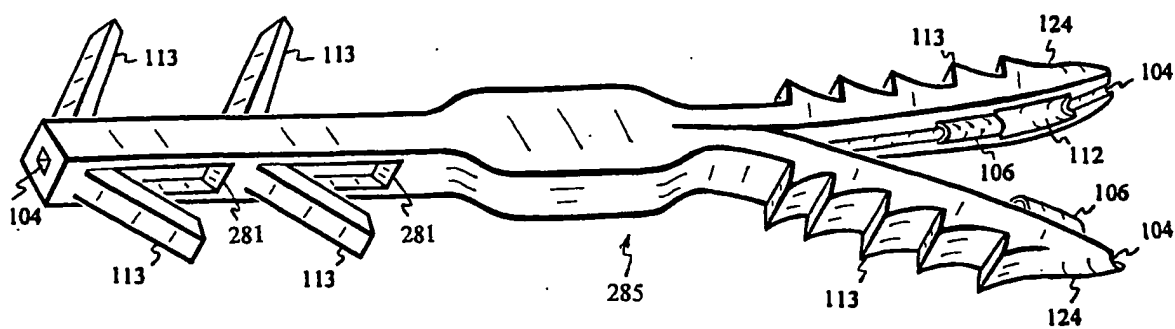


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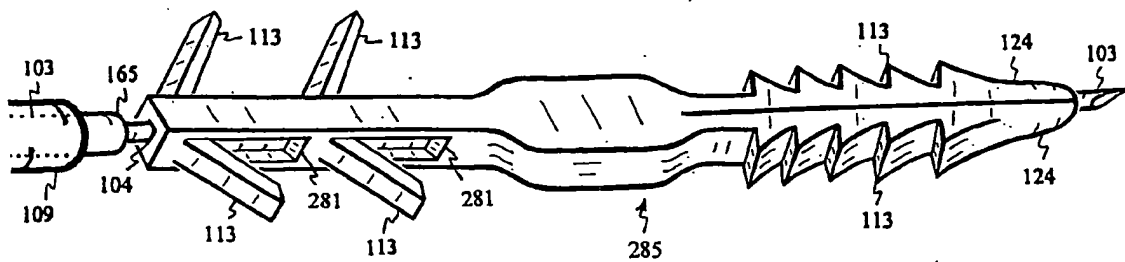


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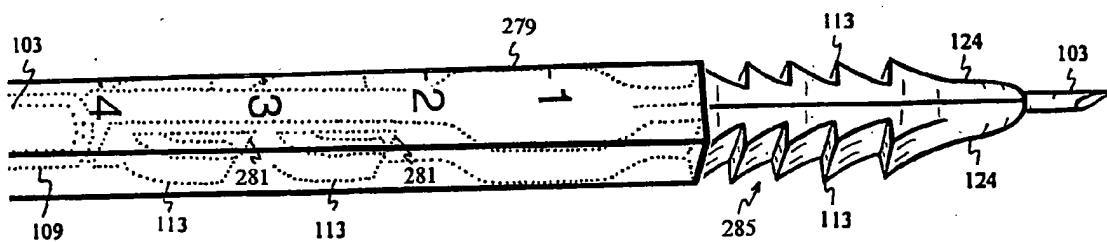


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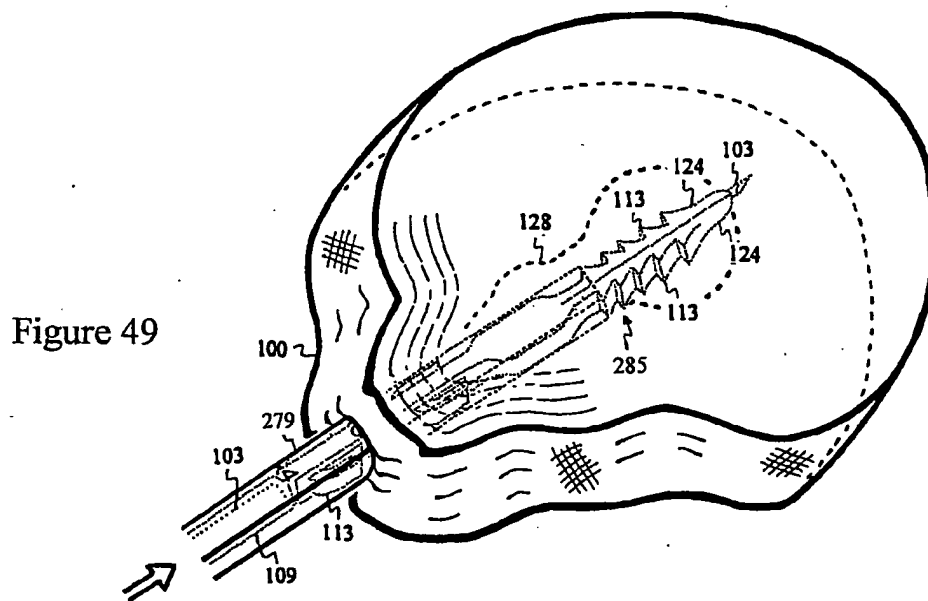


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Figure 50

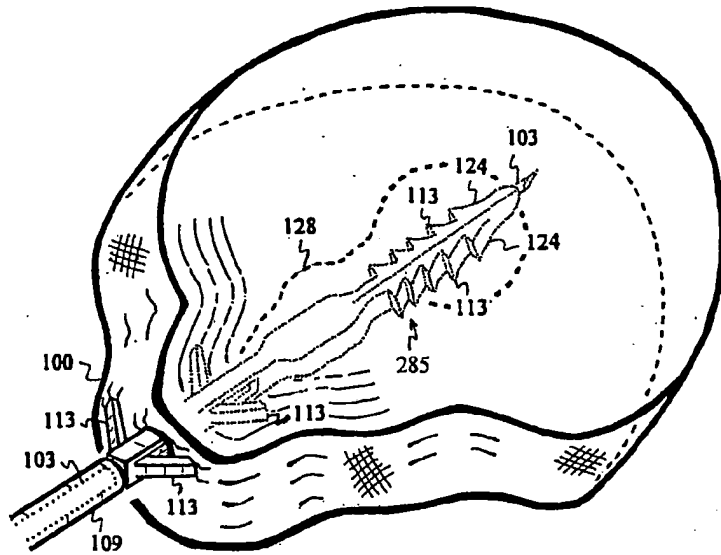


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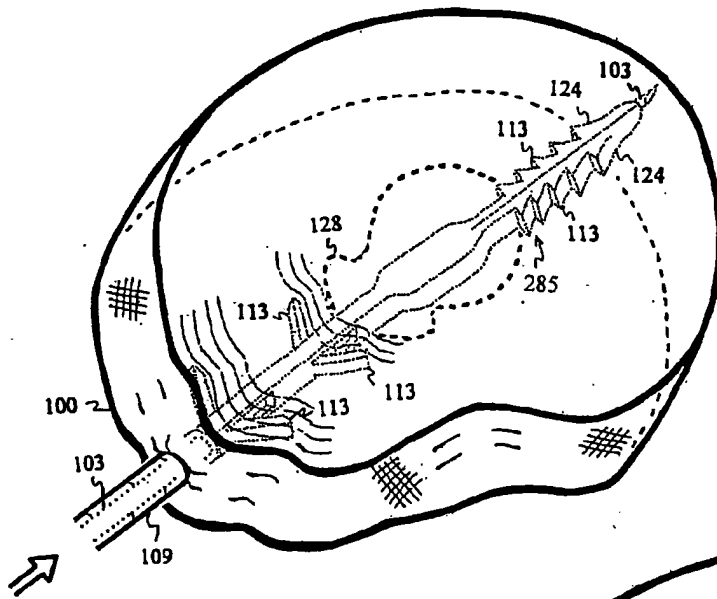
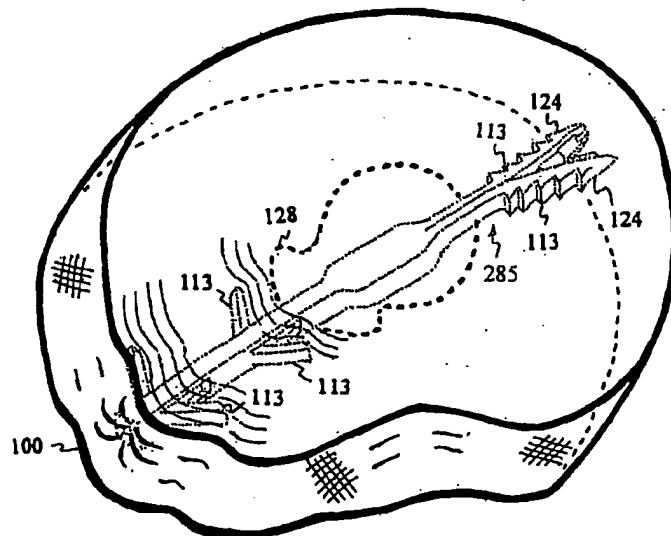


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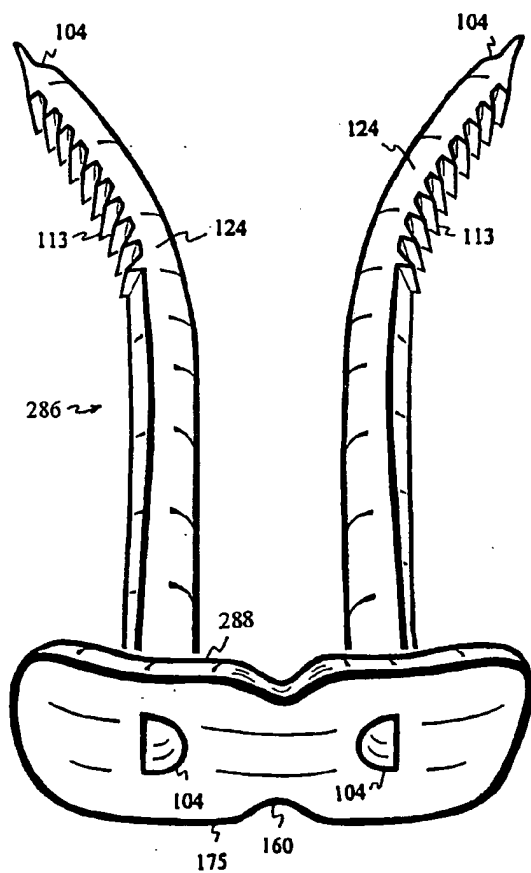


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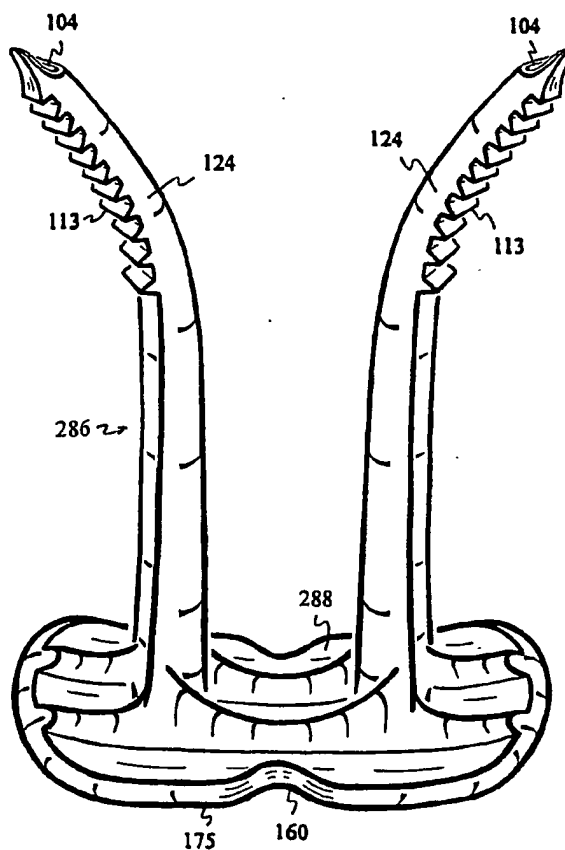


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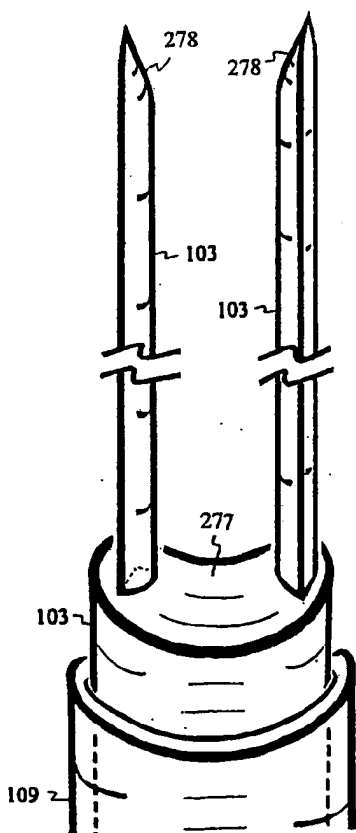


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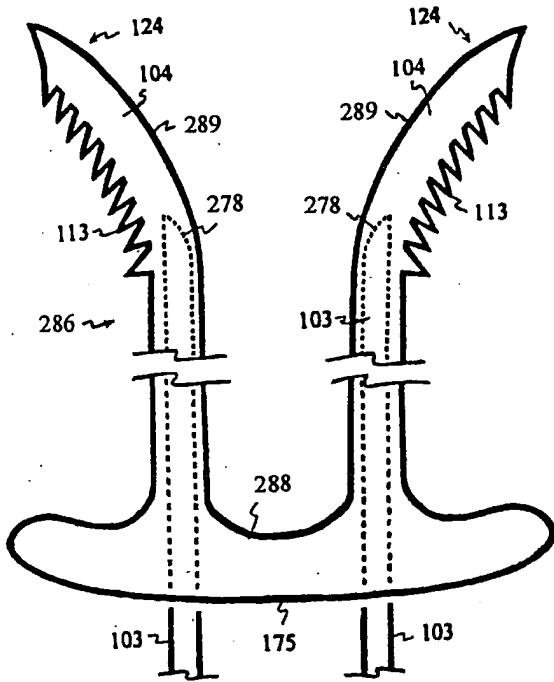


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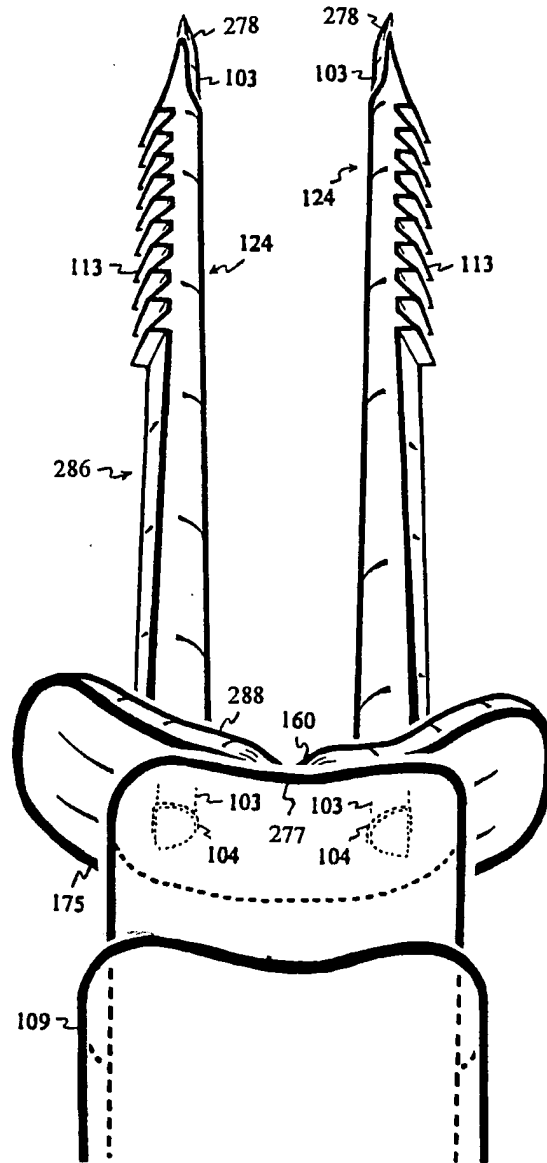


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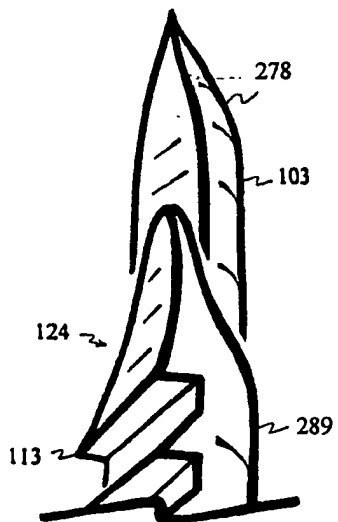


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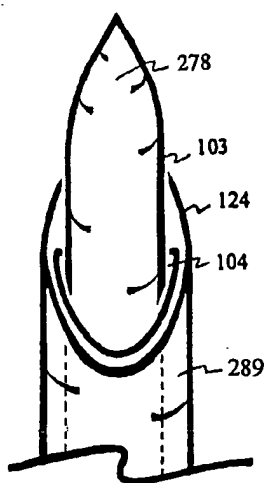


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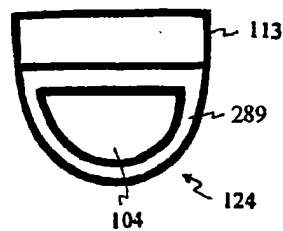


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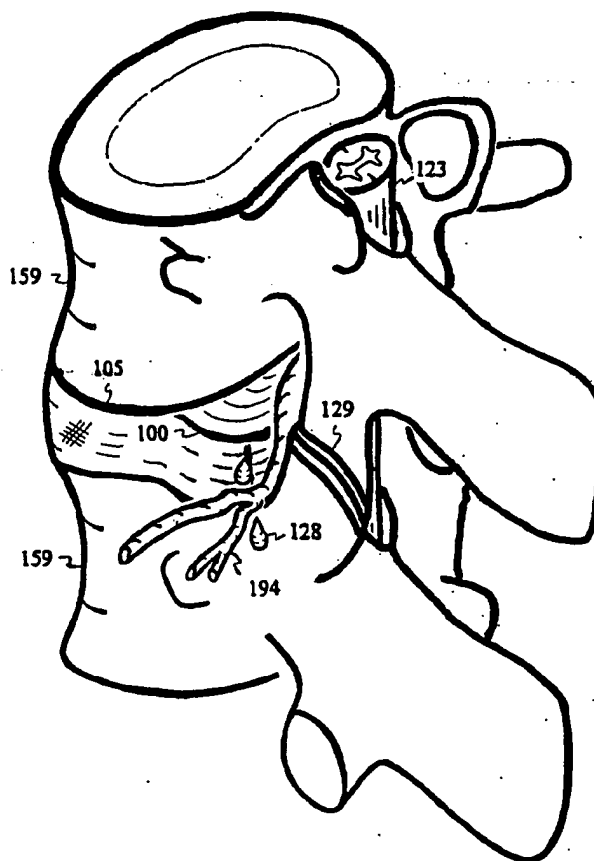


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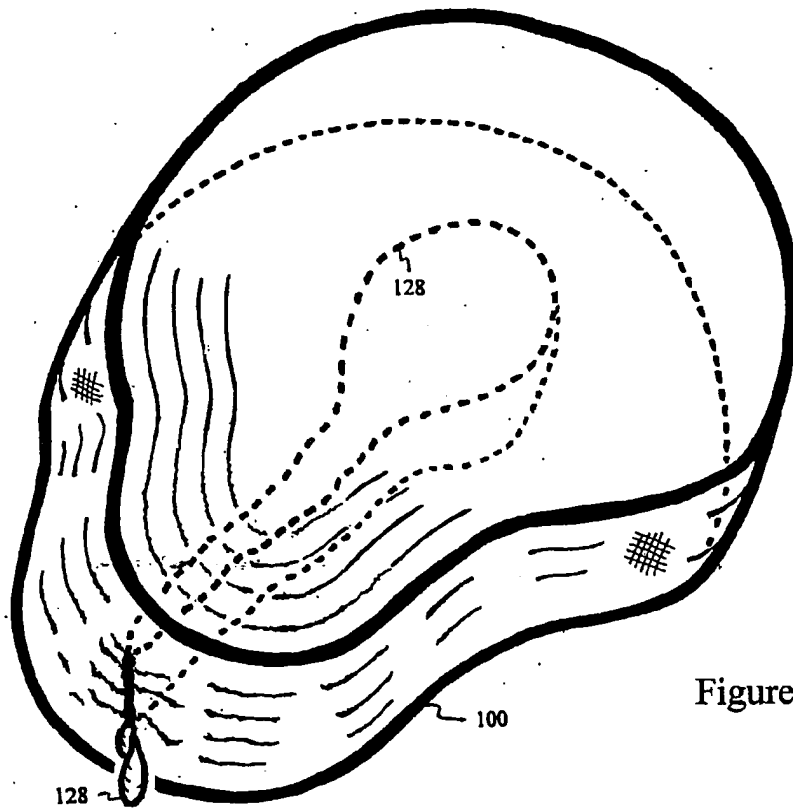


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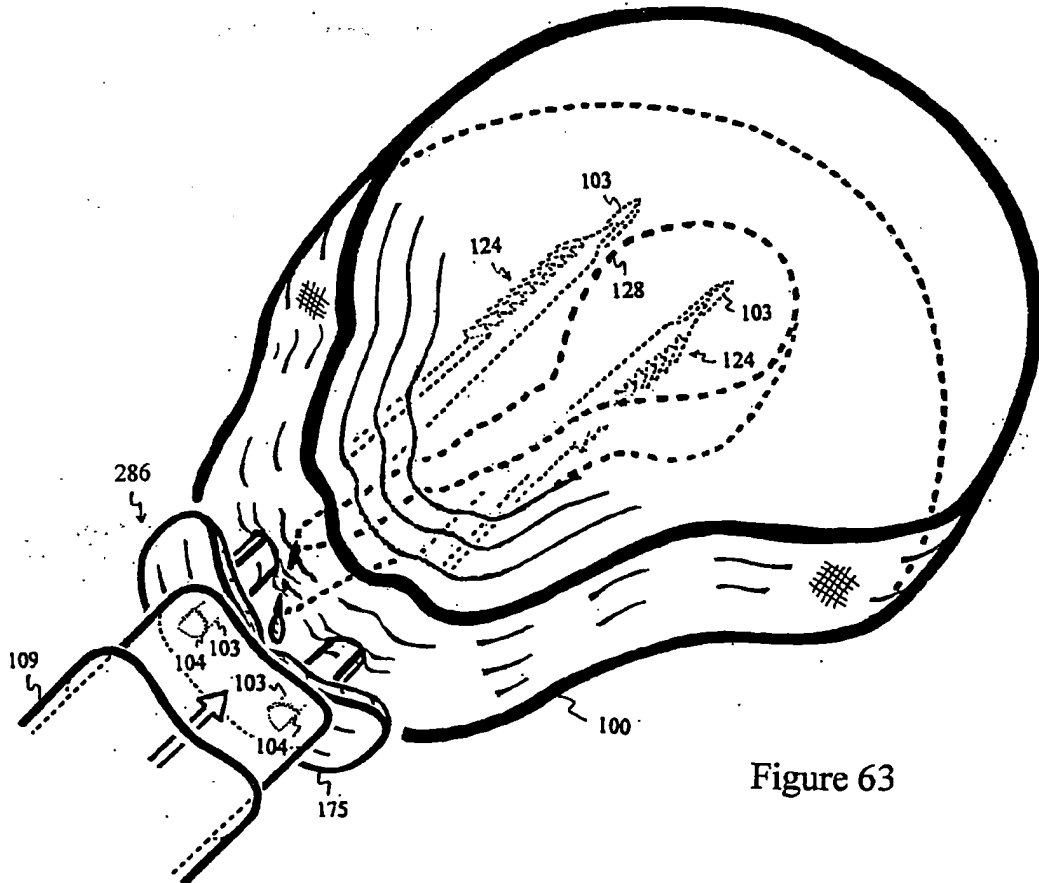


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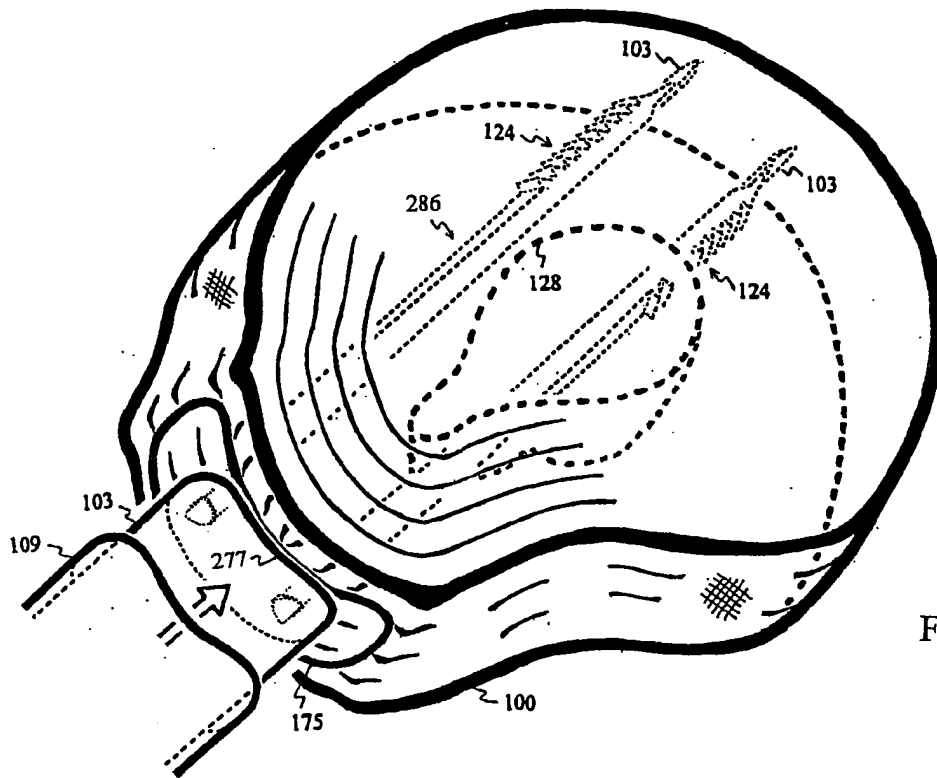
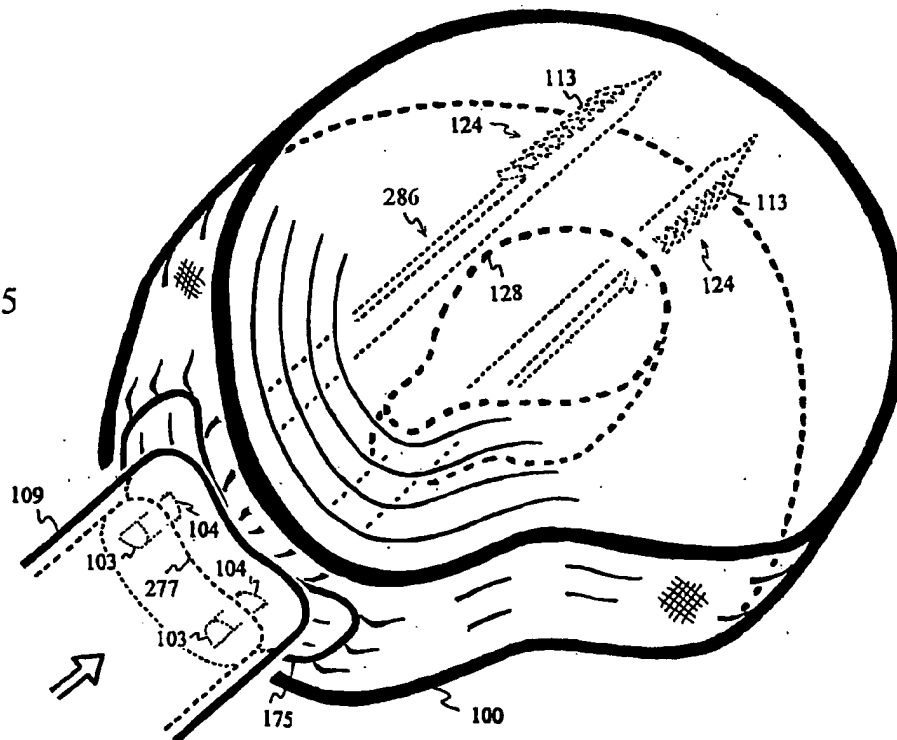


Figure 64

Figure 65



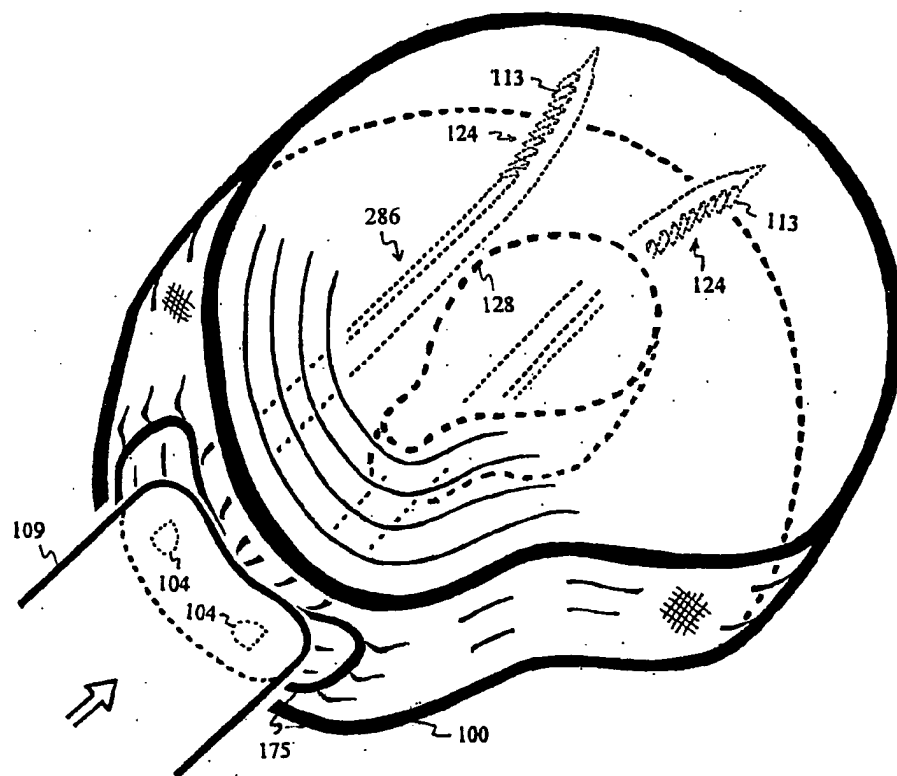
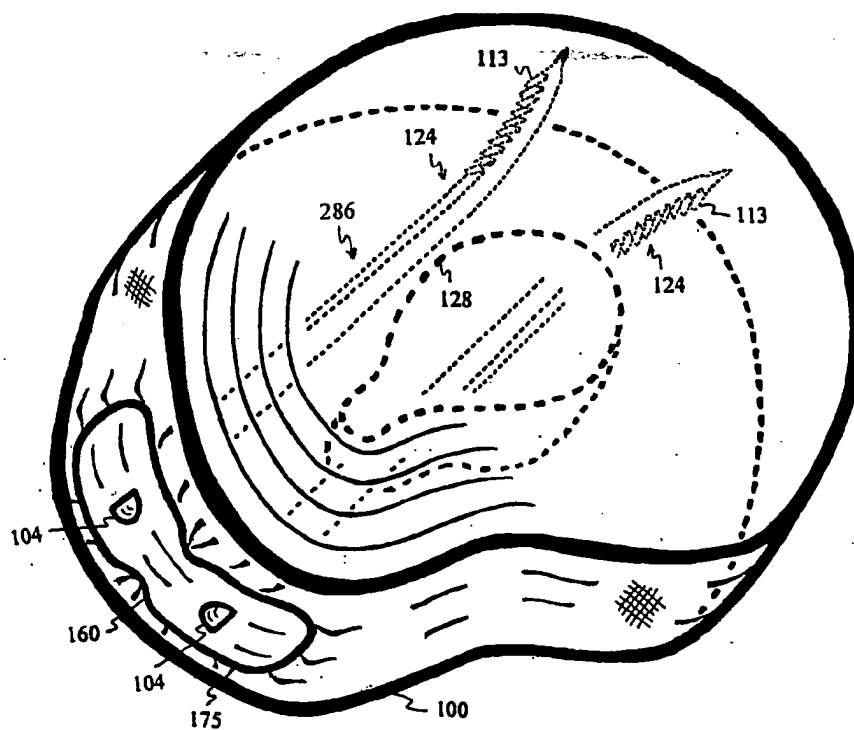


Figure 66

Figure 67



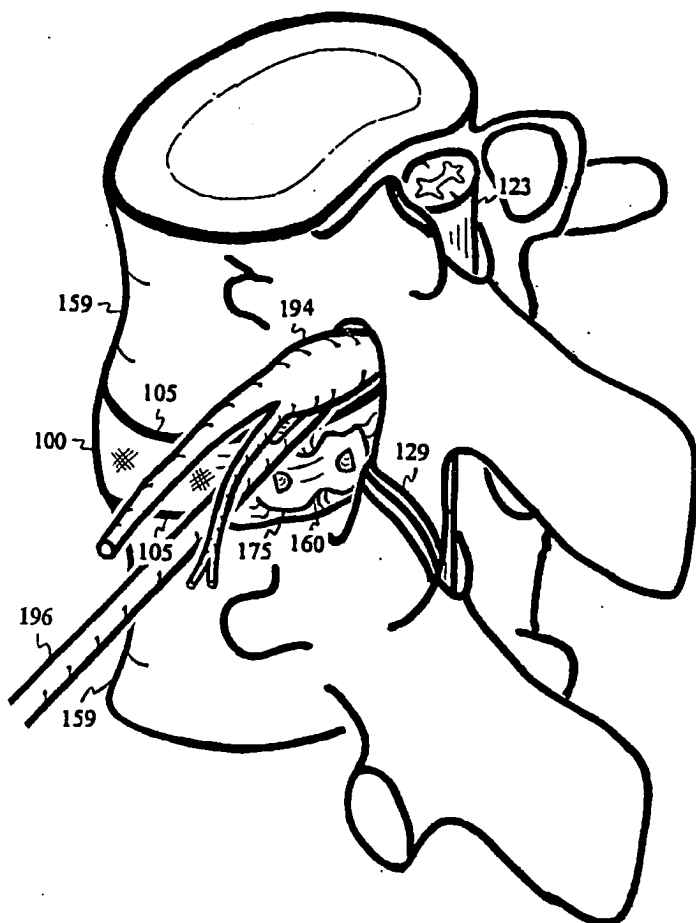
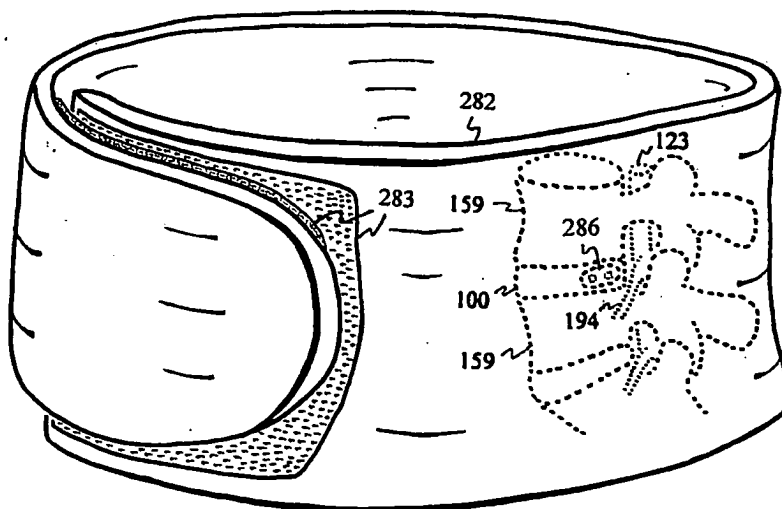


Figure 68

Figure 69



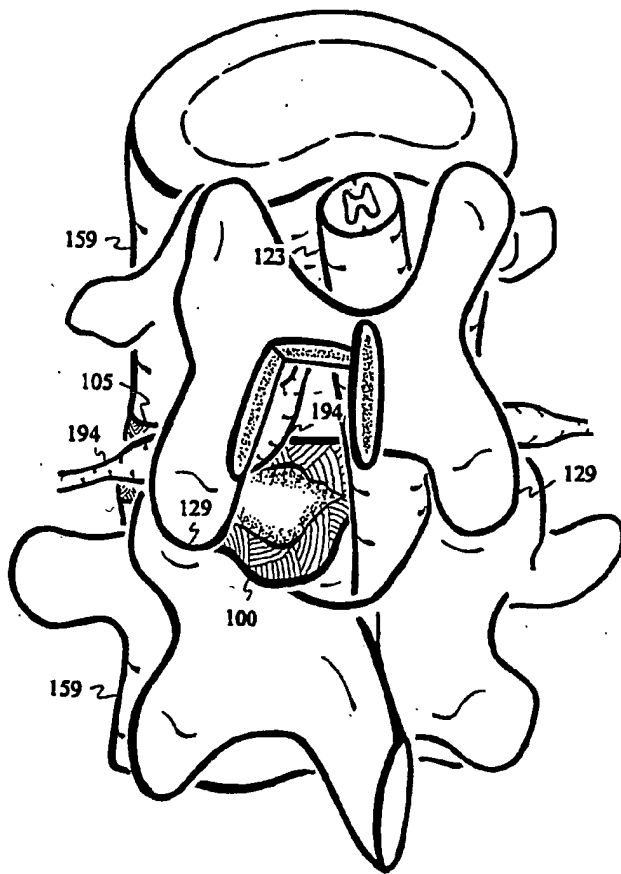


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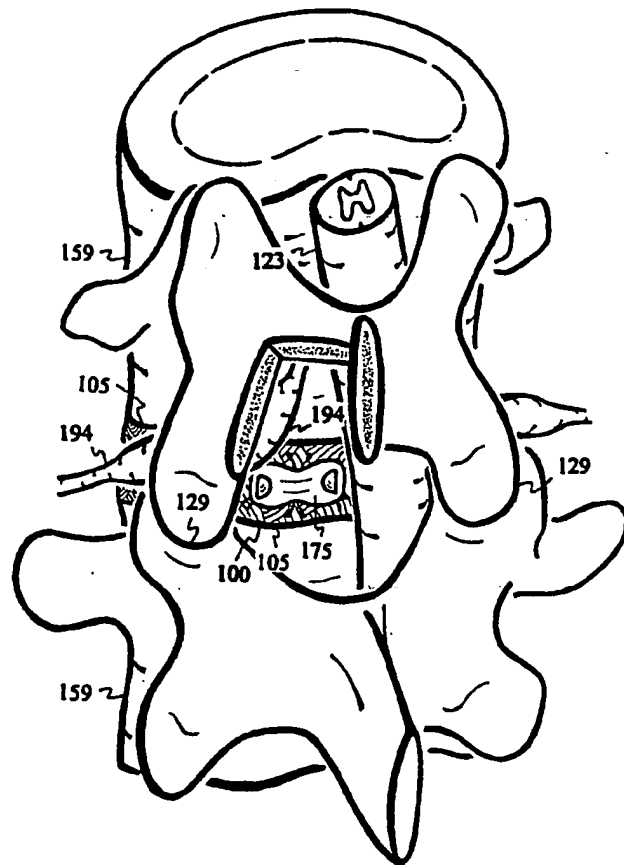


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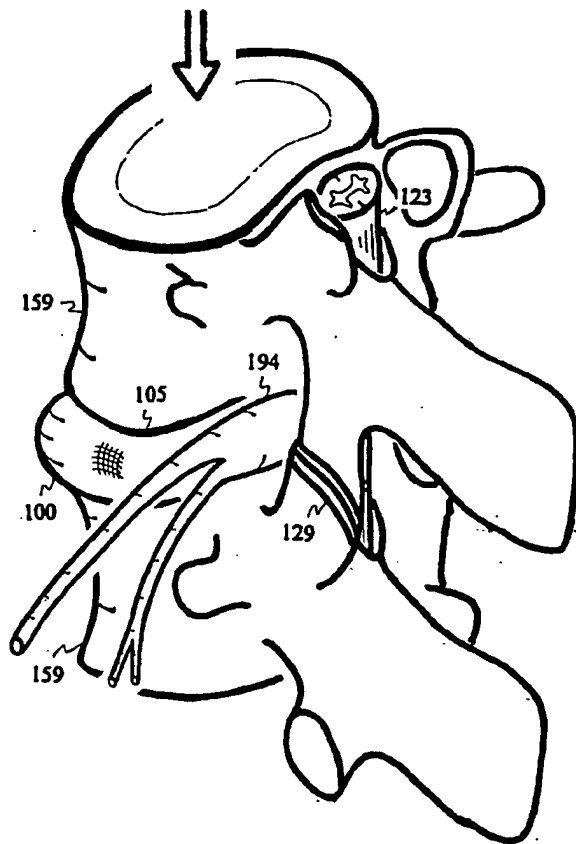


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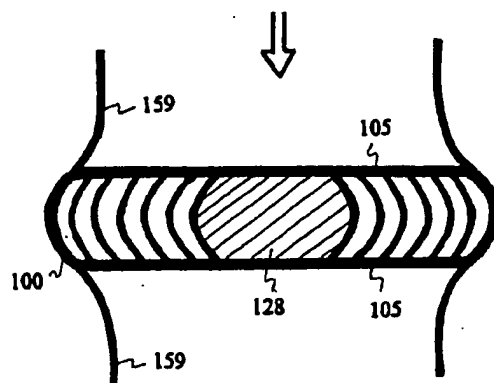


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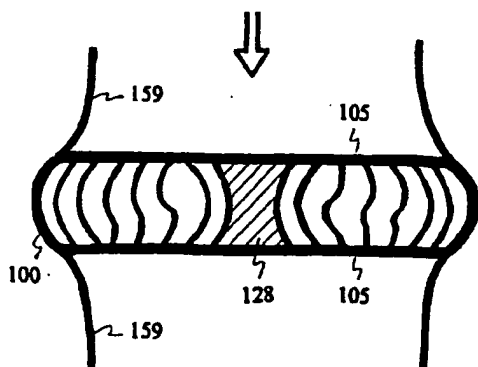


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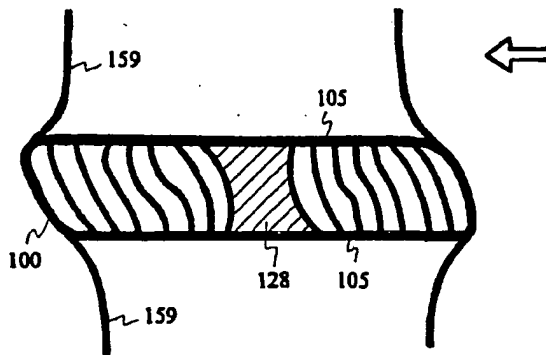


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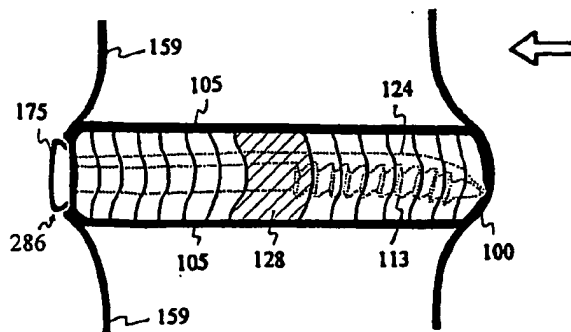
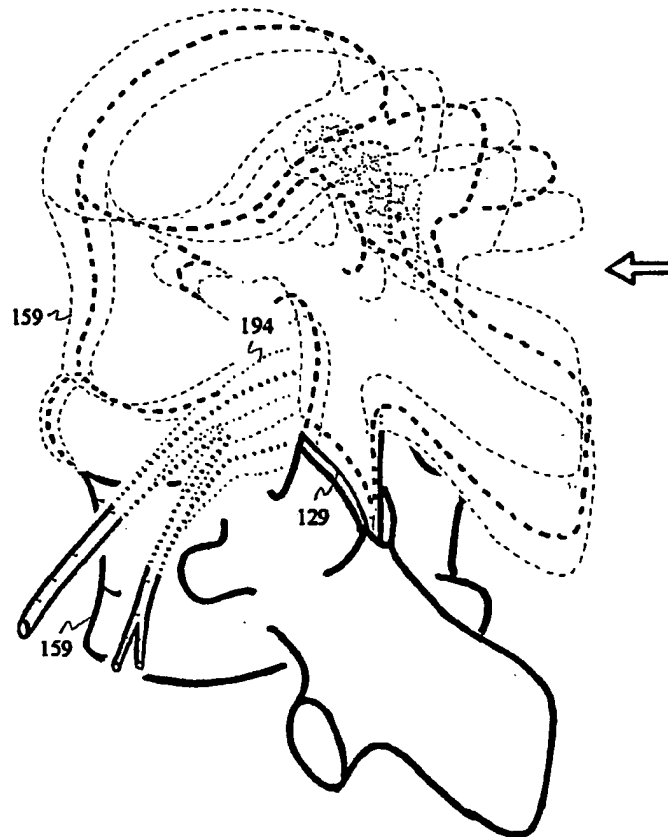


Figure 77

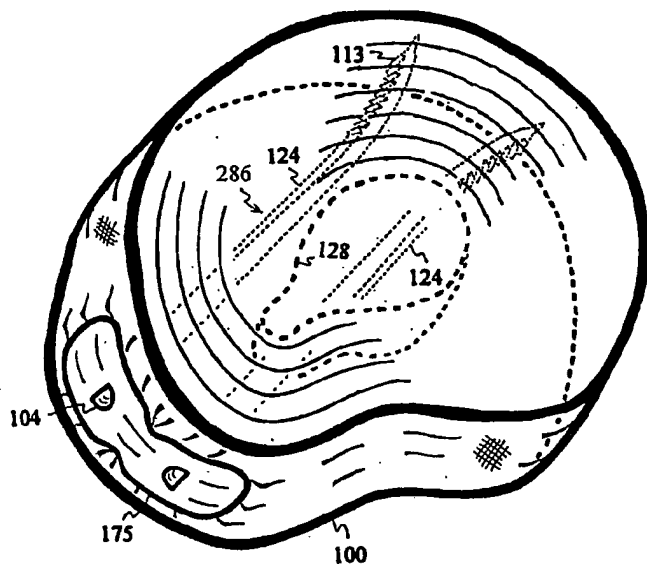


Figure 78

Figure 79

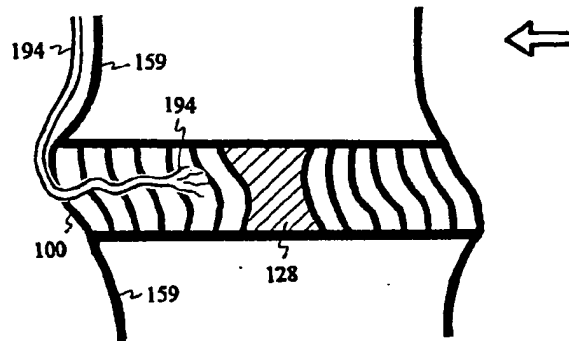


Figure 80

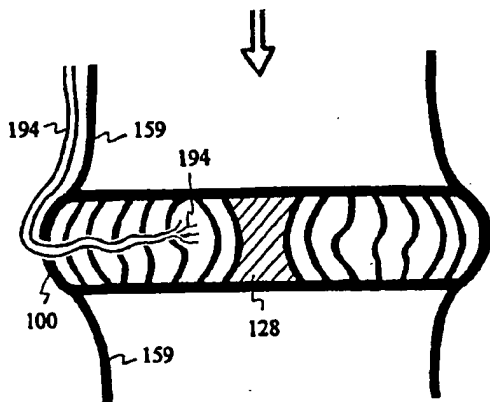
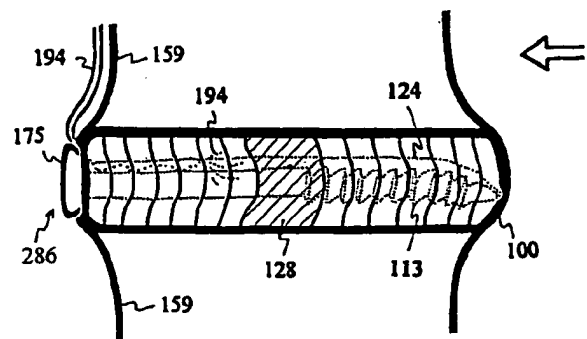


Figure 81



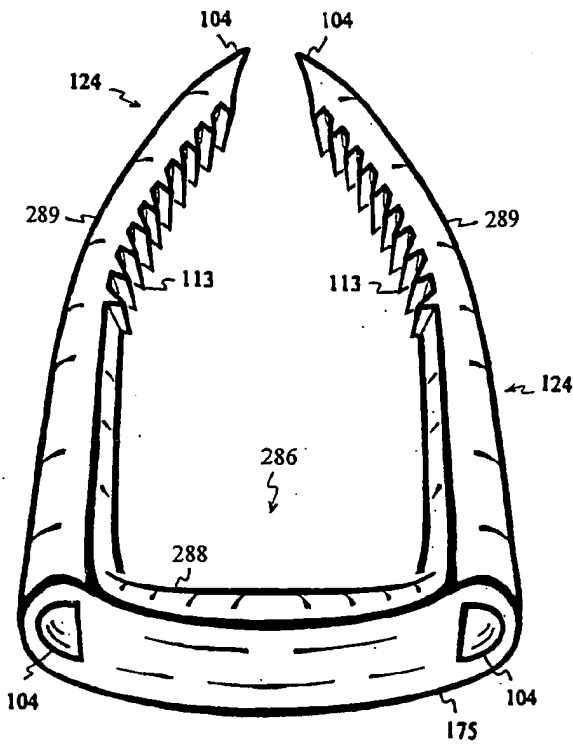


Figure 82

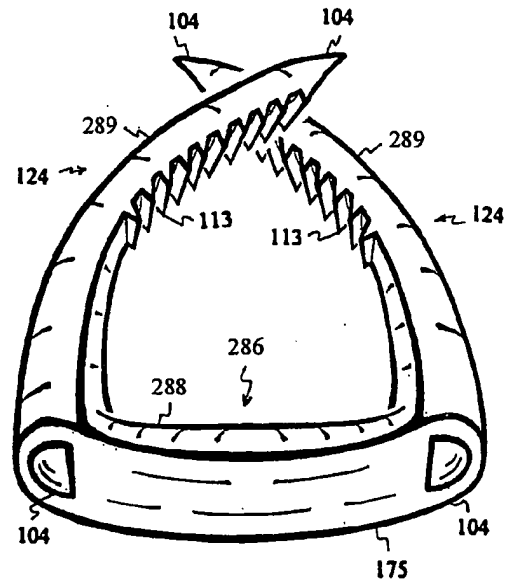


Figure 83

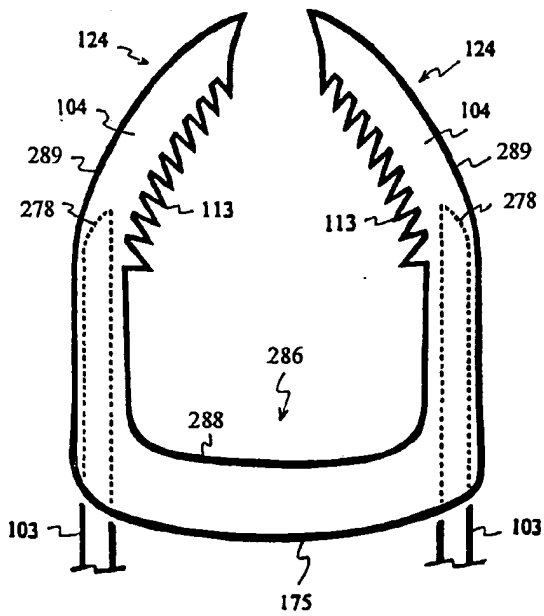


Figure 84

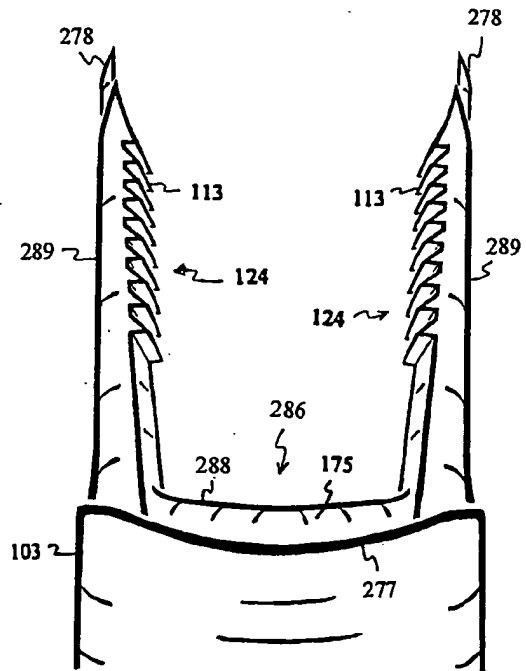


Figure 85

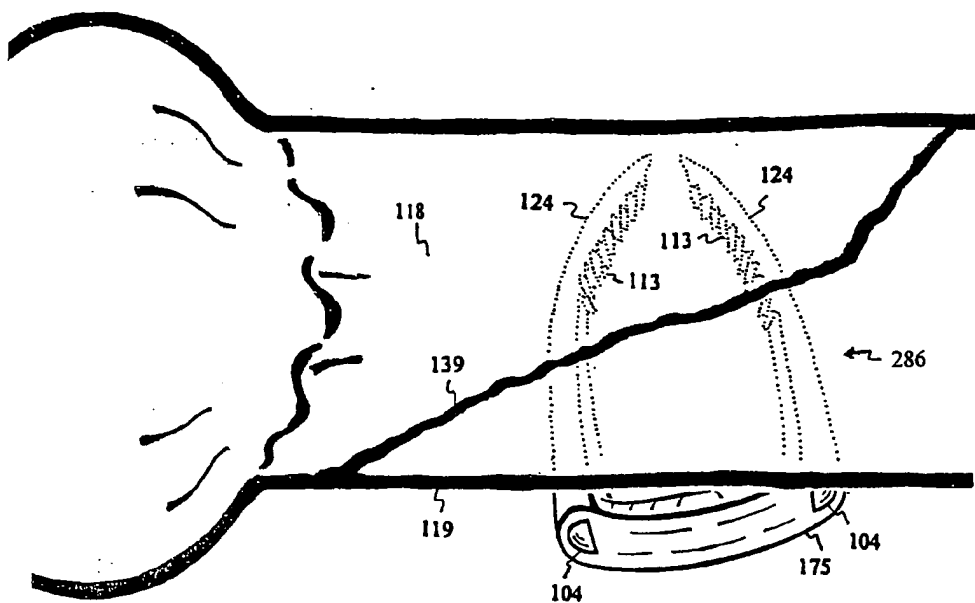


Figure 86

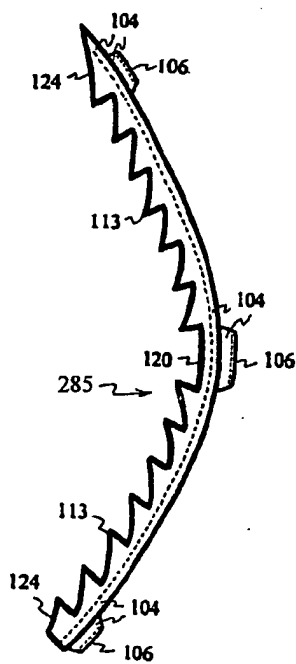


Figure 87

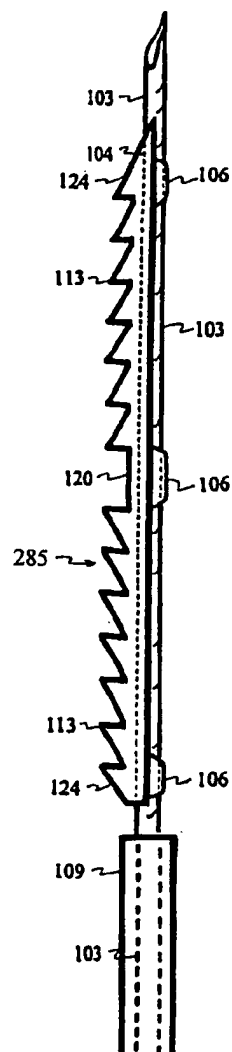


Figure 88

Figure 89

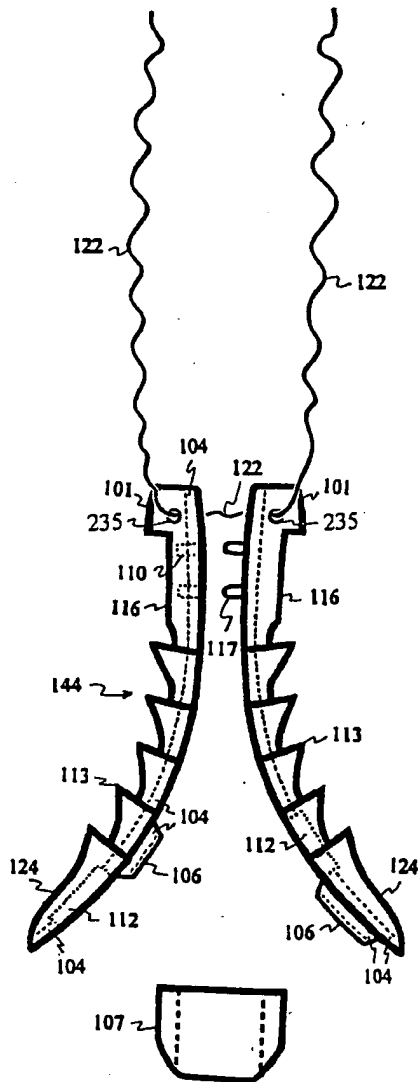


Figure 90

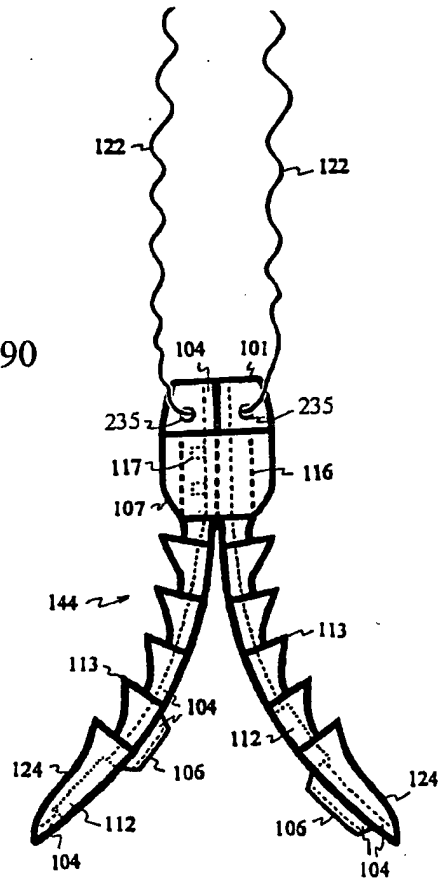
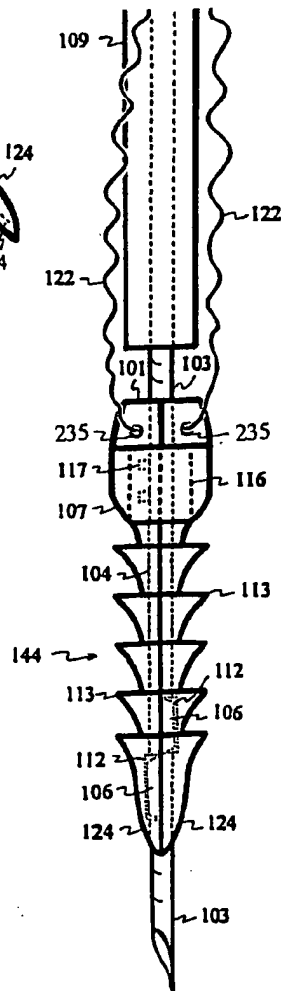


Figure 91



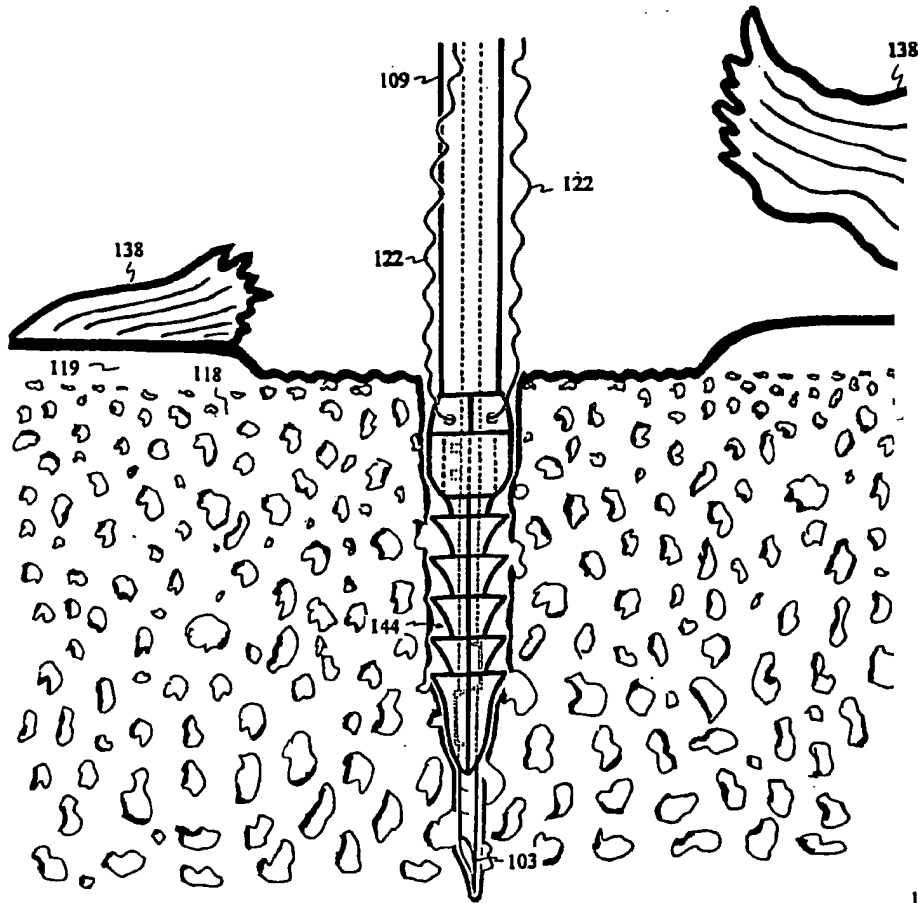


Figure 92

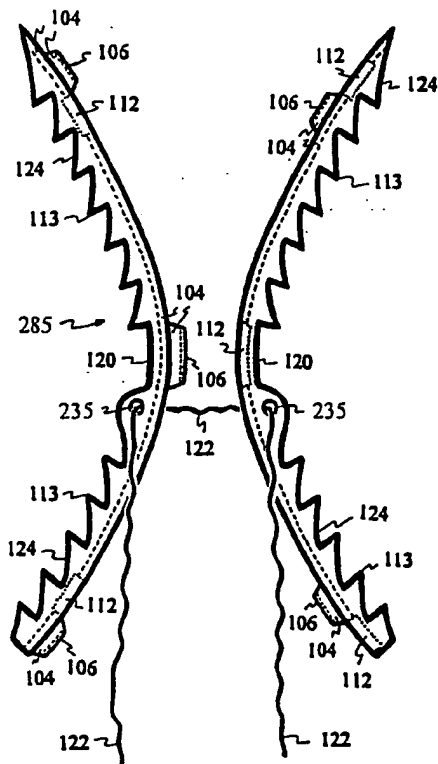


Figure 93

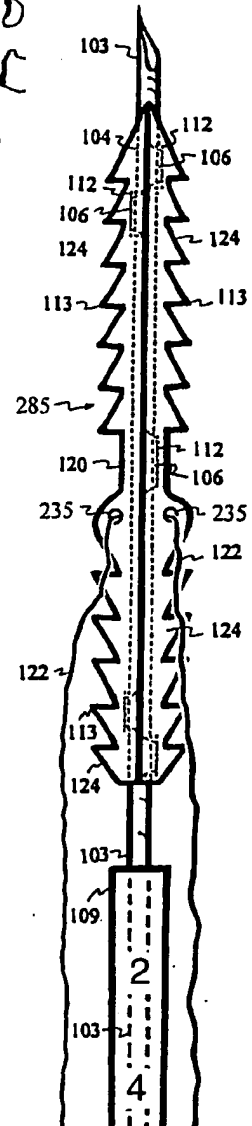
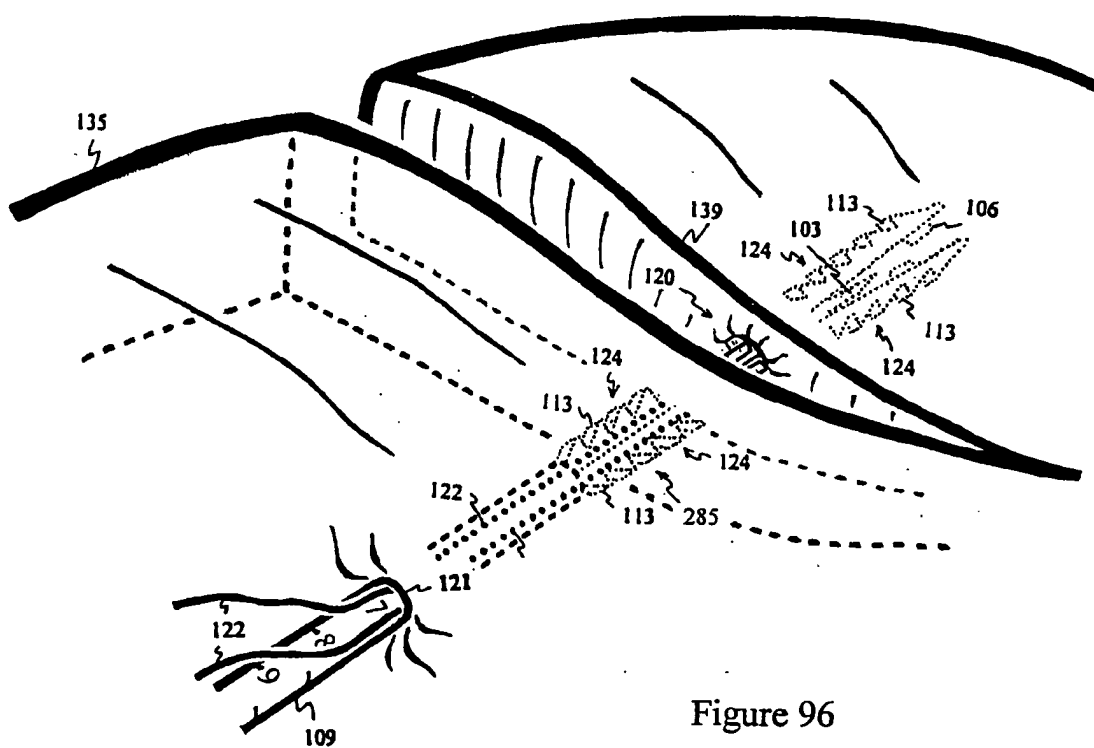
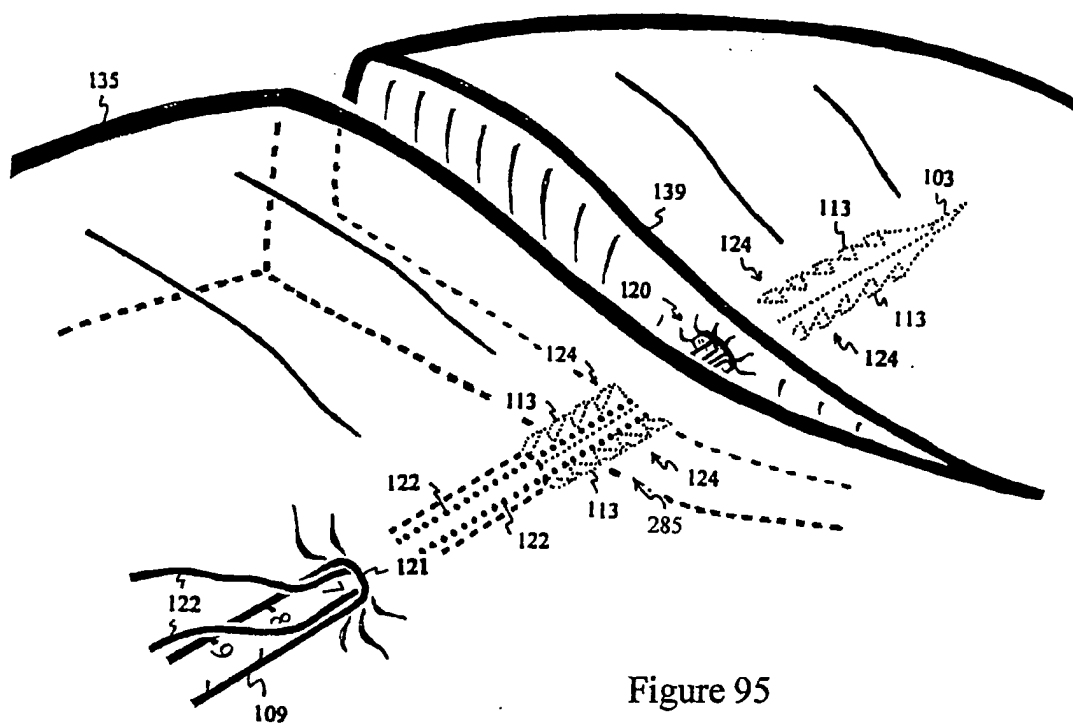


Figure 94



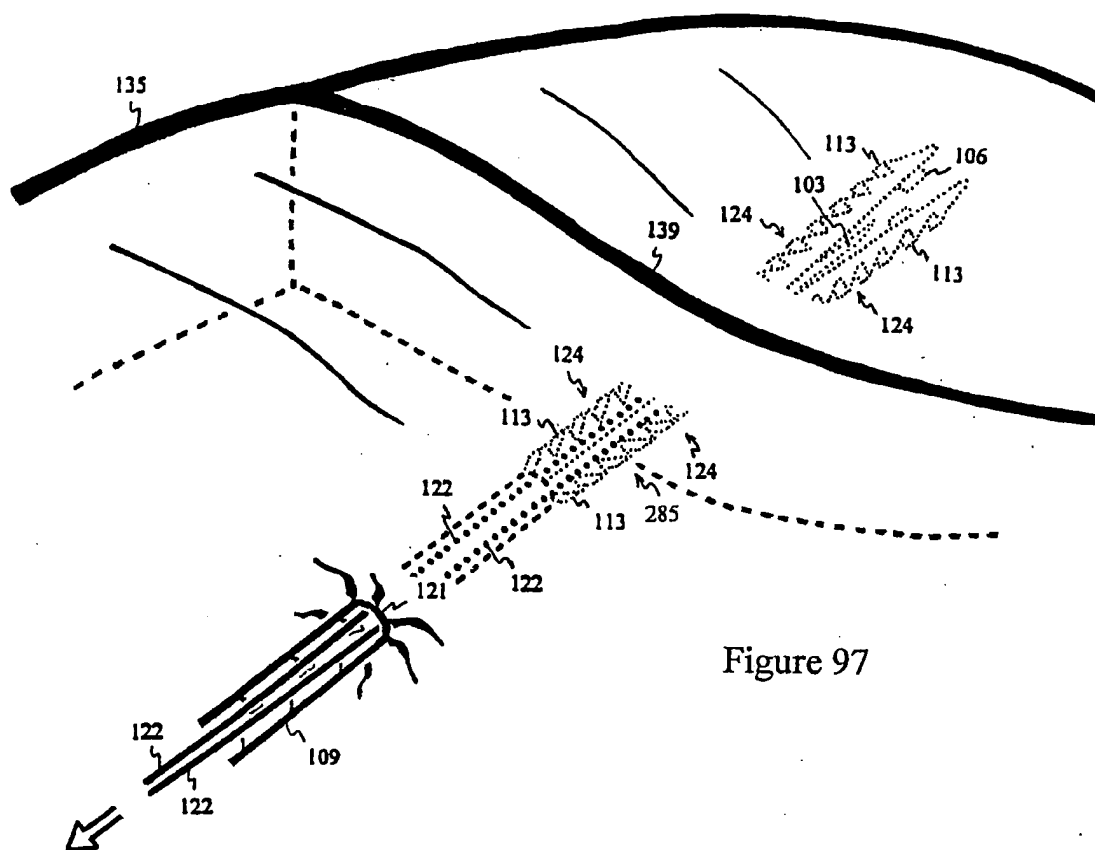


Figure 97

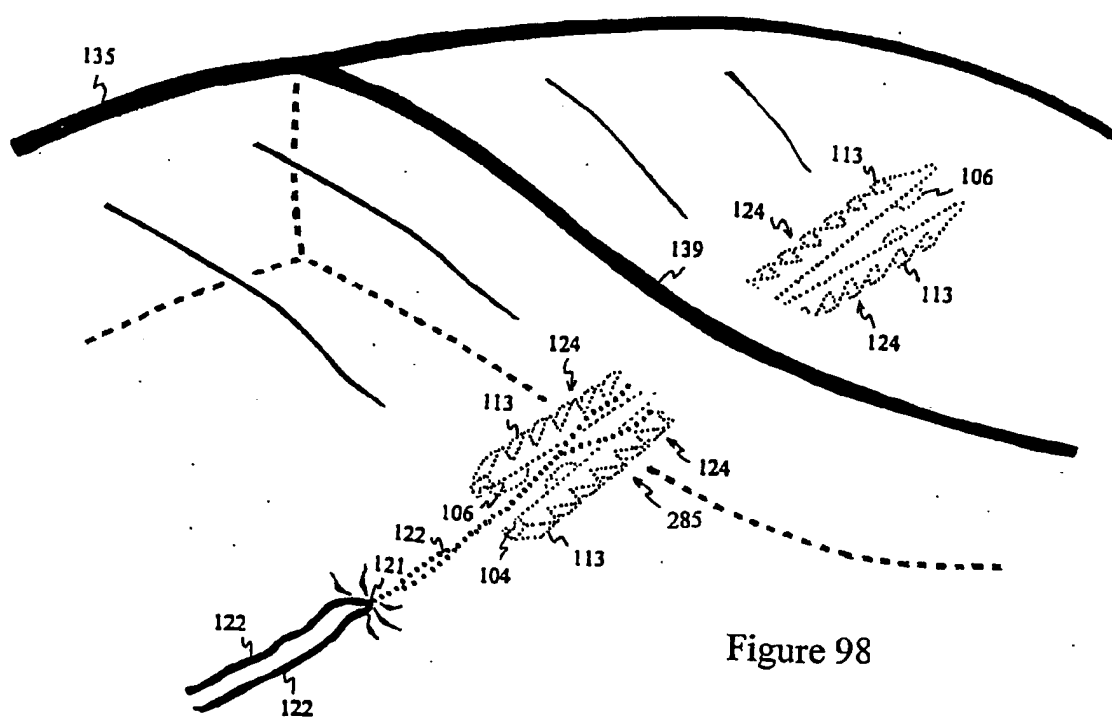


Figure 98

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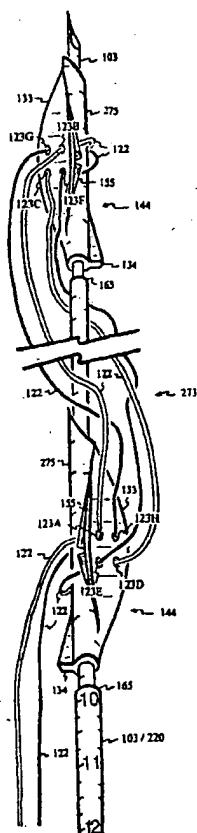
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(54) Title: SUTURE ANCHOR AND APPROXIMATING DEVICE



(57) Abstract: An elastically curved suture anchor is resiliently straightened and delivered into tissue by a needle. When the needle is withdrawn, resumption of the curvature provides leverage for anchor rotation as the attached suture is pulled to fasten the anchor within the tissue. A fin at the proximal end of the anchor further increases the rotational leverage and expedites anchor fastening. When two or more anchors with connecting suture are delivered in series on a needle, the tension of the suture helps to draw the anchors together and approximates the pierced tissue.

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SUTURE ANCHOR AND APPROXIMATING DEVICE

5

FIELD OF INVENTION

This invention relates to suture anchors and minimally invasive methods for delivering and fastening suture within tissue.

BACKGROUND

Suture anchors have been developed for anchoring sutures in endoscopic or
10 arthroscopic surgery through single sided access. Most prior art suture anchors are delivered from a lumen of a needle or a tubular device. Prior art include US patent 4,235,238 by H. Ogiu et al., issued on Nov. 25, 1980, US patent 4,741,330 by J. Hayhurst, issued on May 3, 1988, US patent 4,669,473 by W. Richards et al., issued on June 2, 1987, US patent 5,800,445 by K. Ratcliff et al., issued on September 1, 1998, US
15 patent 5,041,129 by J. Hayhurst et al., issued on August 20, 1991, US patent 5,845,645 by P. Bonutti, issued on Dec. 8, 1998, US patent RE36,974, reissued on Nov. 28, 2000, and US patent 6,312,448 by P. Bonutti, issued on Nov. 6, 2001. Since the anchors reside within the lumen of the delivery device, the size of the needles or tubular members is correspondingly larger, making tissue penetration more difficult and traumatic.

20 Several prior art anchors reside outside and around a needle. For delivery, a push rod is used to push along one side of the suture anchor, sliding along the needle into the tissue. A suture connected at the opposite side of the push rod is used to pull the anchor as the anchor is being pushed by the push rod. A series of patents by P. Bonutti, US patent 5,814,072, issued on Sep. 29, 1998, US patent 5,948,002, issued on Sep. 7, 1999, US
25 patent 6,033,430, issued on Mar. 7, 2000 and US patent application publication number US2001/0002440, publication date: May 31, 2001, proposed the push and pull method to pivot the anchor within tissue. Pivoting of an anchor within tissue is classified as partial-thickness suture fastening. To facilitate instant pivoting, the suture is connected close to both distal and proximal ends of the anchor to provide favorable leverage for anchor
30 rotation. Figure 1 depicts the prior art 235, which has completed the rotation within tissue. The suture 122 is looped near or at both ends of the anchor 235, as depicted in the prior art patents. For favorable leverage, the strands of suture 122 connected to the

anchor 235 are widely spaced apart. As tension is applied to the suture 122, the strands of suture 122 spread open, as indicated by the shaded area 236, opening or pushing out the tissue 130 along the path of anchor 235 entry. Especially within soft tissue, the widely spaced sutures 122 wedge open the tissue directly above the anchor 235. As a result, the pullout strength of the anchor 235 is likely to be low. The probable mode of failure is likely to be anchor 235 pullout, as depicted in Figure 2, rather than suture 122 breakage. While the widely spaced suture 122 provides favorable leverage for rapid rotation, it appears to sacrifice the strength of tissue anchoring.

Another prior art suture anchor, US patent 5,626,614 by C. Hart, issued on May 6, 1997, also resides outside and around a needle. Hart's invention is designed for fastening or proximating tissues separated by two distinct walls, such as the stomach and abdominal walls, using full-thickness fastening. Unfortunately, most tissue within the body adheres to adjacent tissue with no clear separation, space or cavity. Therefore, full-thickness anchor pivoting to fasten or approximate two tissues has limited use.

SUMMARY OF INVENTION

Organs and/or tissues, especially in urology, are virtually adhere to each other. This invention is capable of anchoring a suture in either partial- or full-tissue thickness fastening, without the cumbersome manipulations of the suture or delivery device as described in prior art. In addition, the suture anchor contains a platform designed to improve anchoring strength within tissue.

A curved anchor made with elastic material contains a lumen for the needle. A fin protrudes from one side and a platform covers the opposite side of the anchor. The fin is on the concave side and at the proximal end, while the platform is on the convex side of the curved anchor. A suture passes through an opening in the platform, loops around the concave side of the anchor, and exits through another opening in the platform. As a result, both strands of the suture can be pulled from the convex side of the anchor.

The suture anchor is resiliently straightened by a rigid needle inserted through the lumen of the anchor. The needle contains a widened portion or a step to prevent the anchor from sliding up the needle. The needle is used to deliver the anchor by puncturing into tissue. At a proper depth, the needle can then be withdrawn. The protruded fin is tapered for tissue insertion, but behaves as a tissue snagging barb, hooking onto the tissue

and resisting pullout. As a result, the needle withdrawal strips the anchor off the needle, and at the same time deploys the anchor within the tissue at the proper depth.

The anchor resumes the elastic curvature within the tissue after withdrawal of the rigid needle. The fin at the proximal end of the concave curvature is laterally pressed into the adjacent tissue, while the central portion of the convex curvature connecting to the suture is pushed in the opposite direction further away from the fin. In essence, curvature resumption within tissue increases the distance between the fin and the openings for the suture, as the fin is pressed laterally into the tissue. When the strands of suture are pulled on the convex side of the anchor, the curved anchor begins to rotate within tissue from a vertical, or inserting position, to a horizontal, or fastening position. The platform is also repositioned from vertical to horizontal to greatly resist pullout during tissue fastening and repair.

Multiple anchors can be linked by a suture and delivered in series into tissue. When the suture is pulled, the anchors draw close to each other to shorten or approximate the pierced tissue.

REFERENCE NUMBER

100	Intervertebral disc	125	Suture knot
101	Urethra	126	Cortical bone
102	Urethropelvic ligament	127	Bladder
20 103	Stepped or smooth needle	128	Nucleus pulposus
104	Lumen of suture anchor	130	Soft tissue
109	Plunger	131	Lateral wall of urethra
111	Disc compressor	132	Rectum
112	Bladder neck	133	Platform of anchor
25 113	Mucosa	134	Fin of anchor
114	Vagina	138	Tendon or ligament
115	Pubic symphysis	144	Suture anchor
117	Urine	150	Lumen of urethra
118	Cancellous bone	151	Posterior wall of urethra
30 119	Annular contact surface	152	Anterior wall of urethra
122	Suture	153	Needle indentation
123	Opening for suture	154	Catheter

155	Bend stop	249	Sharp edge
156	Gap of bend stop	250	Suture cutting device
157	Incision	251	External sphincter
159	Handle of positioning device	252	Internal sphincter
5 160	Lifting hand piece	253	Cardinal ligament
161	Uterus	254	Sacrouterine ligament
163	Uterus positioning tool	255	Fascia
164	Suture attachment	256	Ovary
165	Step of trocar or needle	257	Round ligament
10 171	Distal round end	258	Fallopion tube
172	Shaft of positioning device	259	Grasping device
185	Trocar guide	260	Guide arm
188	Psoas major muscle	261	Pointer
196	Retractor	262	Glide track
15 220	Sleeve of trocar or needle	263	Endoscope
221	Grippers on the sleeve	264	Suture gripping device
235	Prior art suture anchor	265	Flap
236	Area of suture spread	266	Cone
237	One-way grip	267	Loop
20 238	Suture passage of the grip	268	Scar tissue
239	Suture lock	269	Lumen of needle
240	Cone hole	270	Collagen bundles
241	Gripper	271	Cervix
245	Knot pusher	272	Adipose tissue
25 246	Inner tube	273	Approximating device
247	Outer tube	274	Retropubic space
248	Side window	275	Body of anchor

55

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 depicts the tissue 130 opening above the prior art anchor 235, caused by spreading 236 of the sutures 122 as tension is applied.

Figure 2 depicts prior art anchor 235 pullout as a probable result of the tissue 130 opening directly above the prior art anchor 235.

Figure 3 depicts a suture anchor 144 with an elastically curved body 275, lumen 104, a fin 134, a relatively flat platform 133 and two openings 123 for a suture 122.

Figure 4 depicts the elastic body 275 being resiliently straightened by a trocar or needle 103 inserted through the lumen 104 of the anchor 144.

5 Figure 5 depicts the resiliently straightened anchor 144 resting on a step 165 of the needle 103.

Figure 6 shows a side view of the anchor 144 with the stepped needle 103. The distal tip of the anchor 144 is beveled. The platform 133 and fin 134 are tapered for tissue penetration.

10 Figure 7 depicts the top view of the anchor 144 with suture 122 exiting from openings 123 on the elliptical platform 133 tapered at both distal and proximal ends.

Figure 8 shows the bottom view of the anchor 144, indicating the tapered distal tip, and looping of the suture 122 under the anchor 144 to distribute suture 122 tension.

15 Figure 9 depicts the rotational direction of the curved suture anchor 144 within tissue, as tension is applied to suture 122.

Figure 10 depicts penetration of the stepped needle 103 loaded with the suture anchor 144 into soft tissue 130.

Figure 11 depicts the anchor 144 resuming the curved configuration and pressing the fin 134 laterally into the tissue 130 after the withdrawal of the stepped needle 103.

20 Figure 12 depicts tension applied to the suture 122 pulling on the curved anchor 144 and driving the fin 134 further laterally.

Figure 13 depicts the tension driven rotation of the anchor 144, orienting the large and relatively flat platform 133 from a vertical to a horizontal position to resist anchor 144 pullout.

25 Figure 14 indicates a normal, well-supported bladder 127 in dashed lines and a descended bladder 127 with a widened bladder neck 112 in solid lines.

Figure 15 shows a failed lumen 100 closure and hypermobility under stress with the urethropelvic ligament 102 pulling the lateral walls 131 of the poorly supported urethra 101.

30 Figure 16 indicates a mid-longitudinal view of Figure 15 and urine 117 leakage during stress with urethropelvic ligaments pulling perpendicularly above and below the plane of the page.

Figure 17 shows a prior art procedure for treating urinary incontinence through a large incision 157 for passing sutures 122 and pulling the vagina 114 forward to support or compress the posterior wall of the urethra 101.

Figure 18 depicts a section of the surgically corrected urethra 101 with sutures 122
5 pulling the vaginal 114 tissue to support and gently compress the urethral posterior wall 151.

Figure 19 indicates lumen 150 closure of the surgically corrected urethra 101 under stress, with urethropelvic ligaments 102 pulling the lateral walls 131 of the supported urethra 101.

10 Figure 20 shows a small incision 157 for inserting the stepped needle 103 with the suture anchor 144 into the vaginal wall.

Figure 21 depicts the urethral posterior wall 151 supported by sutures 122 and anchors 144 within the vagina 114.

Figure 22 indicates a proximal end of a suture anchor 144 with an elliptical lumen 104,
15 sized and configured to fit over a stepped needle 103 with an elliptical cross-section.

Figure 23 shows a lengthened fin 134, sized and configured to fit into an indentation 153 on a stepped needle 103.

Figure 24 depicts a uterine 161 prolapse.

Figure 25 depicts a repositioned uterus 161 pierced with the stepped needle 103
20 through a small incision 157.

Figure 26 depicts uterus 161 fastening with sutures 122 and anchors 144. The suture 122 is knotted 125 onto the ligament or fascia on the abdominal wall.

Figure 27 depicts penetration of the stepped needle 103 with the suture anchor 144 through a torn ligament 138 into decorticated bone 118.

25 Figure 28 depicts the suture anchor 144 resuming some of the curved configuration within the bone 118 after being dislodged from the withdrawn stepped needle 103.

Figure 29 depicts suture 122 tension driving the fin 134 further laterally into the bone 118.

Figure 30 depicts another anchor 114 delivered by the stepped needle 103 through the
30 torn ligament 138 into cancellous bone 118.

Figure 31 depicts a suture knot 125 tied to fasten the torn ligament 138 onto the bone.

Figure 32 shows a bend stop 155 with a closed gap 156 beneath the platform 133 to prevent excessive anchor 144 bending under significant suture 122 tension.

Figure 33 shows a stepped needle 103 resiliently straightening the anchor 144 with the bend stop 155. In the straightened position, the gap 156 is open.

5 Figure 34 depicts a side view of the straightened anchor 144 with an open gap 156 beneath the platform 133.

Figure 35 indicates a bottom view of the straightened anchor 144 showing bend stops 155 with open gaps 156 beneath the platform 133.

Figure 36 shows a straight anchor 144 with a large fin 134 and a tapered proximal end.

10 Figure 37 shows a side view of the straight anchor 144, as shown in Figure 36, with dimensions W_1 , L_1 and L_2 .

Figure 38 shows another straight anchor 144 with elevated suture openings 123.

Figure 39 shows a side view of the anchor 144 with elevated suture openings 123, as shown in Figure 38, with dimensions W_2 , L_1 and L_2 .

15 Figure 40 depicts a curved suture anchor 144 with a protruded suture attachment 164, a fin 134 and a small platform 133.

Figure 41 depicts another curved suture anchor 144 with the protruded suture attachment 164 but without a platform.

Figure 42 shows a curved suture anchor 144 without a fin.

20 Figure 43 depicts a curved suture anchor 144 with a platform 133 on the concave side of the curvature. The fin 134 is made blunt.

Figure 44 shows the suture anchor 144 of Figure 43 resiliently straightened by a needle 103 with a sliding sleeve 220.

25 Figure 45 depicts penetration of the stepped needle 103 with the sleeve 220 to deliver a suture anchor 144 through a bulging intervertebral disc 100.

Figure 46 depicts pushing of the anchor 144 by the sliding sleeve 220 to expel the suture anchor 144 beyond the distal edge of the disc 100.

Figure 47 depicts a disc compressor 111 with two openings 123 for a suture 122 and a cylindrical or blunt region 119 to compress the disc 100.

30 Figure 48 depicts bulge compression by fastening the disc compressor 111 with a suture 122 secured by the anchor 144 outside the disc 100.

Figure 49 depicts portions of two anchors 144 connected by a suture 122 to form an approximating device 273 for tightening or shortening tissue.

Figure 50 shows a double-stepped 165 needle 103 resiliently straightening two anchors 144 with a suture 122 arrangement similar to Figure 49.

5 Figure 51 indicates deployment of the anchors 144 within tissue after withdrawal of the needle 103.

Figure 52 shows orientation of the suture 122 designed to resist sliding through holes 123B and 123G when the anchor 144 is in a vertical or inserting position.

Figure 53 depicts anchors 144 pivoting within tissue as the suture 122 is pulled.

10 Figure 54 shows anchor 144 insertion into tissue 130 with the needle 103, as the initial step for deploying the approximating device 273.

Figure 55 indicates partial withdrawal of the needle 103 to deploy the distal anchor 144 within tissue 130.

15 Figure 56 depicts proximal anchor 144 insertion by pushing the sleeve 220, and distal anchor 144 pivoting by pulling on the suture 122.

Figure 57 shows complete insertion of the proximal anchor 144 into the tissue 130 by pushing the sleeve 220 and pulling suture 122.

Figure 58 indicates withdrawal of the needle and curvature resumption of the proximal anchor 144 within tissue 130.

20 Figure 59 depicts composition of a suture lock 239 with sutures 122 passing through a cone 266 over a one-way grip 237 with individual grippers 241.

Figure 60 shows the lock 239 assembly with the suture 122 fastened between the cone 266 and grippers 241. A plunger 109 is used to advance the suture lock 239.

25 Figure 61 indicates pulling on the sutures 122 and pushing on the plunger 109 against and lock 239 to draw the anchors 144 together as an approximating device 273 within tissue.

Figure 62 depicts knot 125 tying within tissue using a knot pusher 245.

Figure 63 shows an inner tube 246 containing a channel opening from the distal end to a side window 248.

30 Figure 64 shows an outer tube 247 also containing a channel opening from the distal end to a side window 248.

Figure 65 depicts a suture cutter 250 assembled by fitting the inner tube 246 into the outer tube 247 with overlapping side windows 248.

Figure 66 indicates threading a pair of sutures 122 through the distal opening, out the overlapping side windows 248 of the inner tube 246 and outer 247 tube.

5 Figure 67 shows a mid-longitudinal view of the suture cutter 250 with sharp edges 249 at the side windows 248.

Figure 68 depicts cutting of the suture 122 by the sharp edges 249 as the outer tube 247 slides over the inner tube 246.

Figure 69 shows a mid-longitudinal view of Figure 68.

10 Figure 70 depicts suture 122 cutting with the cutter 250 after knots 125 are tied.

Figure 71 indicates retraction of an incision 157 to expose a scarred 268 external sphincter 251, a common cause of anal incontinence.

Figure 72 shows cutting of the sphincter 251 in a prior art surgical procedure.

15 Figure 73 depicts overlapping and suturing the external sphincter 251 to tighten the internal sphincteric muscle 252.

Figure 74 shows a lumen 269 in the needle 103 for delivering radiopaque, echogenic or other tracing agent to guide needle 103 insertion.

Figure 75 shows tightening of the scarred 268 external sphincter 251 with multiple approximating devices 273.

20 Figure 76 depicts a flexible needle 103 with a tapered tip, as a sewing needle, for delivering the approximating device 273.

Figure 77 depicts rotational advancement of the flexible needle 103 between collagen bundles 270 of tendon or ligament 138.

25 Figure 78 depicts a lumen 269 in the rotational needle 103 for delivering radiopaque, echogenic or other tracing agent to guide needle 103 insertion.

Figure 79 indicates a cross-sectional view of the uterine 161 supportive structure, cardinal 253 and sacrouterine 254 ligaments, and fascia 255.

Figure 80 shows insertions of multiple approximating devices 273 into cardinal 253 and sacrouterine 254 ligaments supporting the uterus 161.

30 Figure 81 indicates the ascendant cervix 271 as the result of sutures 122 tightening to plicate the cardinal 253 and sacrouterine 254 ligaments.

Figure 82 depicts partial insertion of the proximal anchor 144 of the approximating device 273 into tissue 130 by advancing the sleeve 220.

Figure 83 shows a prior art suture-gripping device 264 with flaps 265 biased against the upward tensile force applied to the suture 122.

5 Figure 84 indicates the suture gripping device 264 and plunger 109 positioned to tighten the anchors 144 of the approximating device 273 after withdrawal of the needle.

Figure 85 depicts fastening of the approximating device 273 by tying knots 125 beneath the suture-gripping device 264.

10 Figure 86 shows a guide 185 to direct needle 103 insertion along a track 262, with an extendible arm 260 and a pointer 261 to indicate the destination of the needle 103.

Figure 87 depicts needle 103 insertion through the vaginal 114 wall, lateral to the urethra 101 into fascia 255 and adipose tissue 272.

Figure 88 indicates support of the posterior urethral wall 151 by the anchors 144 of the approximating devices 273.

15 Figure 89 also shows support of the posterior urethral wall 151 by tightening or restricting between fascia covering the anterior urethral wall 152 and the vaginal 114.

Figure 90 depicts double approximating devices 273 loaded on a single needle 103.

Figure 91 shows fastening of the double approximating devices 273 after insertion of a single needle 103.

20 Figure 92 shows an inner sleeve 220 for deploying the distal anchor 144 and an outer sleeve 220 for deploying the proximal anchor 144 from the needle 103.

Figure 93 depicts the proximal end of a platform 133 tapered over the proximal end of the body 275 to facilitate pivoting and rotation within tissue.

25 Figure 94 shows the side view of the tapered platform 133 over the proximal end of the body 275 supported by a shape-matching step 165.

DETAILED DESCRIPTION OF THE EMBODIMENTS

A curved anchor 144 is made with elastic material containing a longitudinal lumen or passage 104, a fin 134 at or near the proximal end, and a relatively flat platform 133 on the convex side of the curvature with two openings 123 for a suture 122, as shown in
30 Figure 3. Through the openings 123 on the platform 133, the suture 122 is looped around the concave side of the curved anchor 144 for tension distribution. Figure 4 depicts a relatively rigid trocar or needle 103 inserted through the lumen 104 to resiliently straighten

the elastic anchor 144. The needle 103 is marked with measuring units, visible under endoscope, to indicate depth of needle 103 penetration into tissue. The distal portion of the needle 103 is sized and configured to fit into the lumen 104 of the anchor 144. To prevent the anchor 144 from sliding up the needle 103 during tissue penetration, the cross-sectional diameter of the needle 103 is not uniform. A step 165 on the needle 103, as shown in Figures 4 and 5, blocks the anchor 144 from sliding upward, over the needle 103. Figure 5 depicts the proximal end of the resiliently straightened anchor 144 resting on the step 165 of the needle 103, with the fin 134 protruding over or above the step 165. In essence, the elastic suture anchor 144 has a curved position and a straightened position.

Figure 6 depicts a side view of the curved anchor 144 straightened by the rigid stepped needle 103. The distal tips of the anchor 144, platform 133 and fin 134 are tapered and/or beveled to accommodate tissue penetration. The proximal end of the fin 134 is designed to resist anchor 144 pull out during withdrawal of the stepped needle 103. Figure 7 depicts the top view of the anchor 144 with an elliptical platform 133 tapered at both distal and proximal ends. The tapered distal end of the platform 133 is designed for tissue penetration spearheaded by the stepped needle 103. Figure 8 depicts the bottom view with tapered distal ends of the anchor 144 and the fin 134 for ease of tissue penetration. The suture 122 passes through the openings 123 on the platform 133 and loops under the straightened anchor 144 to distribute tension of the suture 122. Since the suture 122 is not tied to the anchor 144, the suture 122 can slide freely, even after the anchor 144 is fastened within tissue. A sliding suture 144 can be useful, sometimes essential in tissue reattachment or other surgical manipulations.

The fin 134 serves as a reversed barb or a snag, favoring tissue penetration but resisting anchor 144 pullout. The anchor 144 is delivered by tissue piercing with the stepped needle 103, as shown in Figure 5. The depth of anchor 144 insertion is known by the measuring units on the stepped needle 103, as shown in Figures 4 and 5. As the stepped needle 103 is withdrawn, the barb-like fin 134 catches, hooks or snags onto the surround tissue, allowing the anchor 144 to slide off the withdrawn stepped needle 103. The anchor 144 remains in the tissue with the suture 122 attached. In essence, the anchor 144 is delivered in the tissue simply by inserting and withdrawing the stepped needle 103.

Driven by suture 122 tension, the delivered anchor 144 is designed to rotate and fasten within tissue. After withdrawal of the stepped needle 103, the anchor 144 resumes the

curved configuration, laterally pressing the pointed proximal end of the fin 134 into the tissue. Three points curved anchor 144: the suture openings 123 on top of the platform 133, the fin 134 and the distal end of the anchor 144, form a triangle. In essence, the lateral separation between the protruded fin 134 and the suture 122 connecting points or openings 123 increases with resumption of the anchor 144 curvature. The distance, W, between the suture openings 123 and the proximal end of the fin 134, as shown in Figure 9, provides initial rotational torque, when tension is applied to the suture 122 by the surgeon. The tapered proximal end of the platform 133 is shaped for lateral tissue penetration when the anchor 144 is pulled by the suture 122. The curved arrow in Figure 9 indicates the rotational direction of the anchor 144 within the tissue from vertical to near horizontal, about 90°, as a direct response to suture 122 tension, shown as a straight arrow. The fin 134 guides, spearheads and/or prevents the anchor 144 from twisting during rotation or pivoting within tissue, repositioning the platform 133 from being parallel with the suture 122, as shown in Figure 5, to being near perpendicular with the suture 122 for maximum anchoring power. Anchor 144 rotation within the tissue may also be favored if L_1 is longer than L_2 , where L_1 is the distance between the proximal end of the anchor 144 to suture openings 123, and L_2 is the distance between the distal end of the anchor 144 to suture openings 123. However, depending on the size and shape of the platform 133, if L_1 is significantly longer than L_2 , the anchor 144 may over rotate, beyond 90°. As a result, the suture 122 would no longer be perpendicular to the platform 133, and the anchoring strength could possibly weaken.

Partial thickness suturing is common in open surgery, and rotation of the curved anchor 144 within the tissue allows the surgeon to obtain partial thickness suturing in endoscopic, arthroscopic or laparoscopic procedures. The curved suture anchor 144 is designed for: (1) elastically straightening with the stepped needle 103, (2) tissue penetration with tapered distal portions, (3) dislodging with the barb-like fin 134, (4) curvature resumption following needle 103 withdrawal, (5) rotation within the tissue driven by suture 122 tension, and (6) anchoring strength with the large platform 133.

Figure 10 depicts penetration of the stepped needle 103 loaded with the suture anchor 144 into soft tissue 130. A scale on the stepped needle 103 visible to the surgeon measures the depth of anchor 144 insertion. The fin 134 of the anchor 144 protrudes outwardly, catching the tissue 130 and preventing the anchor 144 from pulling out as the

stepped needle 103 is withdrawn. In essence, withdrawal of the stepped needle 103 dislodges or strips off the anchor 144, allowing the suture anchor 144 to remain at or near the intended depth of insertion. Figure 11 depicts resumption of the curved configuration of the anchor 144 after withdrawal of the stepped needle 103. The curvature also provides compression on the fin 134, embedding the fin 134 laterally into tissue 130. Figure 12 depicts tension applied to the suture 122 to pull and rotate the anchor 144 from an insertion or vertical position to an anchoring or horizontal position. The initial lateral mobility is favored by (1) the curvature of the suture anchor 144, and (2) protrusion of the fin 134. During rotation, twisting of the anchor 144 along the longitudinal axis is prevented by the fin 134 and the platform 133 as both laterally penetrate into tissue 130. Figure 13 depicts further tension applied to the suture 122, orienting the platform 133 to nearly perpendicular to the suture 122 under tension. With the large surface area of the platform 133 pressing against the tissue 130, the suture 122 is secured with good anchoring strength for surgical repair. The rotation of the anchor 144 within the tissue provides partial thickness suturing with endoscopic, arthroscopic or laparoscopic capability.

It is widely believed that most of the urinary incontinence in women is related to a descended position of the bladder 127, the funneling of the bladder neck 112 and/or diminished posterior 151 urethral support. The dashed line of Figure 14 indicates the normal position and the solid line depicts a descended position of the bladder 127 with its funnel-shaped bladder neck 112. Figure 15 shows a failed lumen 100 closure and hypermobility under stress with the urethropelvic ligaments 102 pulling the lateral walls 131 of the poorly supported urethra 101. Figure 16 shows the mid-sagittal view of Figure 15 during stress, with urethropelvic ligaments pulling perpendicularly above and below the plane of the page. Figure 16 also indicates that the section of poorly supported posterior wall 151 withdraws from mucosal 113 coaptation, leading to urine 117 leakage.

Numerous existing surgical procedures are designed to treat urinary incontinence. The traditional surgical treatment for urinary incontinence is to add backboard support to the urethral posterior wall 151, usually by repositioning the vagina 114 with sutures 122. Figure 17 indicates the pre-surgical position of the vagina 114 with a dotted line, and that of the urethra 101 and bladder with dashed lines. Figure 17 also shows a large incision 157 required for repositioning and suturing both the vagina 114 and urethra 101 toward

the abdominal wall. The post-surgical positions of the vagina 114 and backboard-supported urethra 101 are depicted with solid lines. The sutures 122 are knotted 125 to fascia or ligament on the abdominal wall. Figure 18 indicates a section of the backboard-supported posterior wall 151. This significantly invasive procedure provides the
5 backboard support needed for lumen 150 closure during stress with concurrent pulling of the urethropelvic ligaments 102 to prevent urine leakage, as shown in Figure 19.

Through a much smaller incision 157, the suture anchor 144 system can provide similar backboard support to the posterior wall 151 of the urethra 101. A catheter 154 is introduced through the urethra 101 into the bladder 127. The descended bladder 127,
10 depicted in dotted lines, is lifted by the pressure against the wall of the vagina 144.

Through the vagina 114, the surgeon can also feel the catheter 154 within the urethra 101 to guide the needle/anchor 103/144 insertion lateral to the urethra 101, as shown in Figure 20, into the vaginal 114 wall. As the stepped needle 103 is withdrawn, the fin 134 hooks onto the vaginal 114 tissue, stripping the anchor 144 off the withdrawing needle 103. The
15 method of guiding the needle 103 with the surgeon's finger is currently being used with the Stamey needle, a prior art device, for repairing stress urinary incontinence. Unlike the Stamey needle, the needle/anchor 103/144 system does not require passing the suture 122 back and forth from the vagina 114 cavity to the abdominal wall. Furthermore, the suture 122 introduced by the Stamey needle is exposed within the vagina, which increases the
20 risk of infection. The suture anchor 144 on the other hand, can be deployed within the vaginal 114 wall, as partial thickness suturing in open surgery. The suture anchor 144 can also be delivered and deployed in the vaginal 114 cavity, as full thickness suturing. Figure 21 depicts four suture anchors 144 fastened within the anterior vaginal 114 wall, providing backboard support to the posterior wall 151 of the urethra 101. The sutures 122 from the
25 anchors 144 are knotted to fascia or ligament, similar to Figure 17, but requiring only a much smaller incision 157. The orientation of the anchor 144 within tissue can be significant. For example, the anchors 144 deployed perpendicular to the urethra 101, as depicted in Figure 21, may provide a more firm backboard support than the anchors 144 deployed parallel to the urethra 101.

30 To prevent twisting between the anchor 144 and needle 103, the lumen 104 of the anchor 144 can be made non-round, elliptical for example, as shown in Figure 22, with the stepped needle 103 sized and configured to fit the lumen 104. Figure 23 shows an

extended fin 134 sized and configured to fit into an indentation 153 on the stepped needle 103. Similarly, an extended portion from the stepped needle 103 can fit into an indentation in the anchor 144 to prevent the anchor 144 from spinning on the stepped needle 103.

5 Figure 24 depicts a patient with uterine 161 prolapse, a common problem in women. Uterine 161 prolapse is normally surgically treated with hysterectomy, removal of the uterus 161, either through vaginal or abdominal incision. The following procedure is ideally used in conjunction with the ligament-tightening procedure described in Figures 80 and 81. Figure 25 depicts lifting and repositioning of the uterus 161 with a uterine tool
10 163 containing a blunt distal end 171, a shaft 172, a handle 159 and a lift 160. The stepped needle 103 with the suture anchor 144 is then inserted through a small incision 157, guided by an endoscope, into the repositioned uterus 161. As the stepped needle 103 is withdrawn, the fin 134 hooks onto the uterine 161 tissue, dislodging the anchor 144 from the withdrawn needle 103. The needle 103 and anchor 144 insertion procedure is
15 repeated, and the sutures 122 are knotted 125 on the fascia or a ligament on the abdominal wall, as shown in Figure 26, similar to the suture 122 tying for correcting urinary incontinence. Other supporting structures, such as the round ligament and broad ligament of the uterus, may also be suitable for fastening the suture 122 to and supporting the repositioned uterus 161.

20 The suture anchor 144 can also be used in orthopaedic repairs. Figure 27 depicts penetration of the stepped needle 103 and anchor 144 through a torn ligament 138 into freshly decorticated cancellous bone 118. The stepped needle 103 also contains a sleeve 220, freely sliding over the stepped needle 103. The position of the ligament 138 can be manipulated and maintained with grippers 221 on the distal end of the sleeve 220, as the
25 stepped needle 103 is withdrawn. During needle 103 withdrawal, the fin 134 acts as a barb, hooking onto the cancellous bone 118, and stripping the anchor 144 off the withdrawing needle 103. Figure 28 depicts curvature resumption of the suture anchor 144 within the porous cancellous bone 118 after having slid off the withdrawn stepped needle 103. Figure 29 depicts tension applied to the suture 122, pulling on the curved anchor
30 144 and driving the fin 134 further laterally. The platform 133 of the anchor 144 provides a large surface area to press against the bone 118 and resist pull out. Figure 30 depicts another anchor 114 delivered by the stepped needle 103 through the torn ligament 138

into the cancellous bone 118. The stepped needle 103 is then withdrawn with the second anchor 114 also fastened within bone 118. Figure 31 depicts suture knot 125 tying to fasten the torn ligament 138 onto the bone. In arthroscopic surgery, slip knots 125 are most frequently tied and delivered to the surgical site with a knot 125 pushing device. The fastened ligament 138 will eventually heal and reattach onto the cancellous bone 118. In essence, the sutures 122 and anchors 114 are merely used to maintain the position of the torn ligament 138; reattachment and healing occur naturally with the surgically inflicted bleeding bone 118. Therefore, both the anchors 144 and sutures 122 can be made with biodegradable materials to prevent device migration with time.

The anchoring strength of the suture anchor 144 can be further improved. The anchor 144 reaches full anchoring strength as the anchor 144 forms almost a T-configuration or is perpendicular with the suture 122, as shown in Figure 13. With excessive tension on the suture 122, the elastic anchor 144 may curve further, or even fold into a V-configuration. As a result, the anchoring strength would greatly decrease. To prevent the anchor 144 from excessive bending or folding, bend stops 155 can be added along both sides of the anchor 144 to increase rigidity and anchoring strength of the anchor 144. Figure 32 depicts the bend stop 155 with a gap or V-groove 156 beneath the platform 133. When the suture anchor 144 is in the curved configuration, the gap 156 is closed to resist further bending of the anchor 144, as depicted in Figure 32. As the elastic anchor 144 is resiliently straightened by the stepped needle 103, the gap 156 is opened, as shown in Figure 33. Figure 34 depicts the side view of the resiliently straightened anchor 144, showing the open gap 156 of the bend stop 155 beneath the platform 133. Figure 35 depicts the bottom or belly view of the resiliently straightened anchor 144, showing the bilateral bend stops 155 and open gaps 156. The bend stops 155 are designed and positioned to limit or resist excessive anchor 144 bending to maximize anchoring strength.

A straight and rigid anchor 144 with the fin 134 can also rotate within tissue by utilizing the tension applied to the suture 122. As mentioned, the curvature of the anchor 144, as shown in Figure 9, increases the distance, W, to provide additional torque for lateral rotation. For a rigid anchor 144, as shown in Figure 36, a larger and more protruded fin 134 may adequately provide torque for the anchor 144 rotation within the tissue. Figure 37 depicts the side view of the rigid anchor 144 showing a distance, W₁, measured from the proximal tip of the fin 134 to the suture opening 123. The distance,

W₁, provides the initial rotational torque as tension is applied to the suture 122 by the surgeon. By elevating the suture openings 123 from a protrusion, a rigid anchor 144, shown in Figure 38 with side view in Figure 39, provides an even greater distance, W₂, for greater initial rotational torque. The fin 134 can be made pointed or angled, as shown in
5 Figures 36 to 39 to facilitate lateral tissue penetration and anchor 144 rotation. Rotation of the anchor 144 within tissue is also favored when $L_1 > L_2$, where L_1 is the distance between the proximal tip of the fin 134 and the suture openings 123, and L_2 is the distance between the distal end of the anchor 144 and the suture openings 123. The tapered proximal ends, as shown in Figures 36 and 38, also help to facilitate lateral insertion into
10 tissue during anchors 144 rotation.

Several derivatives may provide adequate anchoring strength for the suture 122. Figure 40 depicts a suture attachment 164 without threading through the platform 133. For light duty suture 122 anchoring, the platform 133 may not be necessary. Figure 41 shows an anchor 144 with the fin 134 but without a platform. Figure 42 shows a curved
15 anchor 144 without a fin. With a curvature built into the anchor 144, it may be sufficient to provide initial torque to rotate the anchor 144 within tissue when tension is applied to the suture 122.

The suture anchor 144 may also be used for full thickness anchoring. Figure 43 depicts a curved suture anchor 144 with a platform 133 on the concave side of the
20 curvature. The fin 134 is made blunt to avoid damage to adjacent tissue. The anchor 144 is loaded onto the stepped needle 103 with a sleeve 220 capable of sliding over the stepped needle 103, as shown in Figure 44. The sleeve 220 is similar to that shown in Figure 28 for holding and manipulating tissue. For full thickness suture 122 anchoring, the sleeve 220 can also be used to push the anchor 144 off the stepped needle 103 and
25 deploy the anchor 144 outside the tissue. The protruded fin 134 can provide an additional function, as a contact point for the sleeve 220. Figure 45 depicts a cross section of a bulging L4-5 intervertebral disc 100 located between psoas major muscles 188. Under fluoroscopic guidance or other means, the stepped needle 103 carrying the anchor 144, as shown in Figure 44, is delivered through a small posteriolateral incision, into the bulging
30 annulus and nucleus pulposus 128, as shown in Figure 45. The advancement of the stepped needle 103 stops as the distal tip of the stepped needle 103 exits the disc 100. The sliding sleeve 220 is used to push and expel the anchor 144 with the attached suture

122 out of the disc 100. Especially with a radiopaque coating on the anchor 144, it is possible to see the orientation of the anchor 144. When tension is applied to the suture 122, the platform 133 of the anchor 144 is likely to conform and press against the outer surface of the disc 100, as shown in Figure 46. Otherwise, the orientation of the anchor 144 can be corrected by advancing the distal tip of the sleeve 220 to manipulate the anchor 144 and pull on the suture 122 until the suture anchor 144 is properly positioned. Both the stepped needle 103 and sleeve 220 are withdrawn after proper deployment of the anchor 144.

Figure 47 depicts a curved disc compressor 111 with two openings 123 for the suture 122 and a round or blunt annular compressing region 119. Figure 48 depicts knot 125 tying and bulge compression of the fastened disc compressor 111. The suture 122 is secured with full thickness anchoring by the anchor 144 and compressor 111. The bulge is compressed and fastened to alleviate pain from nerve impingement.

Two suture anchors 144 with unique suture 122 arrangement between them can be loaded in series on a stepped-needle 103 to be deployed within tissue. As the suture 122 is pulled by the surgeon, the anchors 144 draw close to each other, pulling in or approximating the inserted tissue. Figure 49 depicts portions of two anchors 144 connected by a suture 122 through holes 123A, 123B, 123C, 123D, 123E, 123F, 123G then 123H. Proximal ends of the suture 122 are threaded through a plunger 109. The holes 123B, 123C, 123F and 123G are angled to facilitate sliding of the suture 122 after anchor 144 rotation. The suture 122 between the holes 123D and 123E forms a stationary loop beneath the proximal anchor 144. As the suture 122 is being pulled and the plunger 109 is being pushed against the proximal anchor 144, the strands of suture 122 will slide from 123F to 123G and from 123C to 123B. With the stationary loop beneath the proximal anchor 144, the anchors 144 will draw close to each other to approximate, compress or plicate (fold) the inserted tissue. The distal and proximal suture anchors 144 with the suture 122 form an approximating device 273 designed for minimally invasive use.

Two resiliently straightened anchors 144 are loaded in series on a double-stepped 165 needle 103, as indicated in Figure 50. Similar to Figure 49, the suture 122 is threaded through holes 123A, 123B, 123C, 123D, 123E, 123F, 123G then 123H. For clarification, the suture 122 from holes 123A to 123D is white and from holes 123E to

123H is black. Both white and black sutures 122 are slack to clarify points of origin. The distal end of the proximal anchor 144 is tapered for lateral tissue penetration. The lumen 104 of the distal anchor 144 is smaller than the lumen 104 of the proximal anchor 144, each corresponding to the sizes of the distal and proximal steps 165 of the needle 103.

- 5 The distance between the steps 165 can be pre-set or fixed to deliver the anchors 144.

As the fins 134 of the distal and proximal anchors 144 snag into tissue, the needle 103 is withdrawn to deposit both anchors 144 with the connecting suture 122, as shown in Figure 51. Both anchors 144 resume their curved configuration. In vertical or insertion position, the angled suture holes 123B and 123G of the distal anchor 144 are designed to resist suture 122 sliding and to favor pivoting of the distal anchor 144, as shown in Figure 52. The rotation of the distal anchor 144 creates tension on the suture 122 connecting holes 123C to 123D and 123F to 123E, as shown in Figures 49 and 53. The tension of the sutures 122 lifts the proximal anchor 144 by the loop beneath holes 123D to 123E, as shown in Figures 53 and 49. As a result, the proximal anchor 144 also rotates, laterally pressing the pointed distal end into the tissue, with the fin 134 behaving like a rudder to direct rotation.

The proximal anchor 144 can also be inserted by a sliding sleeve 220, rather than by the stationary second step 165 of the needle 103. Figure 54 shows a stepped needle 103 insertion to deliver the distal anchor 144 into the tissue 130. As the tissue 130 is snagged by the fin 134, partial withdrawal of the needle 103 deposits the distal anchor 144 within tissue 130, as indicated in Figure 55. The proximal anchor 144 is delivered by pushing the sleeve 220 and pulling the suture 122, as shown in Figure 56. Suture 122 pulling also initiates pivoting of the distal anchor 144. Figure 57 shows complete insertion of the proximal anchor 144 into the tissue 130. The needle 103 is then withdrawn to deposit the proximal anchor 144, as shown in Figure 58, to complete the installation of the approximating device 273.

The approximating device 273 can be tightened and maintained under tension. A one-way suture lock 239 prevents backsliding during tying and allows further tightening of the suture 122 to fasten the approximating device 273. Figure 59 depicts the composition of a suture lock 239 with a pair of sutures 122 passing through a hole 240 of a cone 266 into a loop 267 of an one-way grip 237 with individual grippers 241, then threaded through a passage 238 at the proximal end of the grip 237. The suture 122 passed through the loop

267 helps to direct the one-way grip 237 into the cone 266. The passage 238 of the grip 237 provides a foundation for suture knot 125 tying. The loop 267 and passage 238 also keep the pair of sutures 122 apart to obtain maximum locking strength within the cone 266. The cylindrical grippers 241 are arranged in angle, layers, sized and configured to fit within the cone 266. Each layer of the grippers 241 are tapered, narrow at the top and widened at the base, biased against backsliding of the suture 122 but allowing further suture 122 tightening. Figure 60 shows the lock 239 assembly with the pair of sutures 122 fastened between the cone 266 and biased grippers 241. The pair of sutures 122 is inserted into a plunger 109. The plunger 109 is bilaterally tapered at the distal end, as shown in Figure 60, for pushing against the proximal end of the one-way grip 237 without interfering with the pulling of the suture 122 to tighten the approximating device, as shown in Figure 61. As an optional procedure, slipknots 125 can be tied then delivered by a knot pusher 245 onto the proximal end of the one-way grip 237, as shown in Figure 62.

Cutting the excess suture 122 beneath the tissue helps to conceal the entire approximating device 273, which may be advantageous since exposure of the non-degradable suture 122 can promote infection. A suture 122 cutting device 250 contains an inner tube 246 and outer tube 247. Figure 63 shows a channel open from the distal end of the inner tube 246 to a side window 248 of the suture cutter 250. Figure 64 shows the outer tube 247 also containing a side window 248. The inner tube 246 is tightly fitted inside the outer tube 247 with overlapping side windows 248, as shown in Figure 65, to form the suture cutter 250. The suture cutter 250 is a relatively thin tubular device. The excess suture 122 is threaded through the distal opening and out the overlapping side windows 248 of the inner tube 246 and outer tube 247, as shown in Figure 66. By straightening and holding onto the proximal ends of the excess suture 122, the cutter 250 can slide along the suture 122 into tissue through the entry punctured by needle 103 and anchors 144. Figure 67 shows a mid-longitudinal view of the suture cutter 250 with sharp edges 249 at the side windows 248. As the outer tube 247 slides against the inner tube 246 or vice versa, the sharp edges 249 behave like scissors, cutting the sutures 122 extending out of the side windows 248, as shown in Figure 68. Figure 69 shows a mid-longitudinal view of suture 122 cutting by sliding the outer 247 and inner tube 246 against each other. Figure 70 depicts suture 122 cutting with the device 250 after knot 125 tying. The cutter 250 is then withdrawn from tissue. As a result, all components are concealed

within the tissue to complete the installation of the minimally invasive approximating device.

One of the most common causes of anal incontinence is scarring of the external sphincter from childbirth. The scarred tissue 268 of the external sphincter 251 can be revealed beneath adipose tissue 272 with retractors 196 opening a semi-circular incision between the vagina 114 and the rectum 132, as shown in Figure 71. Currently, the scarred sphincter 251 is cut, as shown in Figure 72. Then the scarred tissue 268 is overlapped, sutured and knotted 125 to tighten around the internal sphincter 252 beneath, as indicated in Figure 73. The tightness of the sphincteric repair is judged by the feel of the surgeon's finger. After surgical repair of the sphincter 251, painful defecation is inevitable. Infection is also common.

Sphincter 251 repair can be minimally invasive using the approximating devices 273. To guide the needle 103 into the proper location, radiopaque, echogenic or other tracing agents can be injected through a lumen 269, as shown in Figure 74, as the needle 103 advances into the body. Within the loosely packed adipose tissue 272, the injected tracing agent is likely to diffuse quickly. However, within highly structured and relatively dense tissue, such as muscle, tendon, ligament or organ, diffusion of the tracing agent is limited, so it might be possible to indicate the shape of the tissue, an important criterion for verifying the target site for suture 122 anchoring.

The muscular external sphincter 251 encircles the rectum 132 beneath the adipose tissue 272, as shown in Figures 71 and 75. With guidance, the needle 103 is laterally inserted between the vagina 114 and rectum 132 to bridge both sides of the loose external sphincter 251. The needle 103 can be made with a slight curvature for puncturing through skin and adipose tissue 272, then into both sides of the loose sphincter 251. The anchors 144 can be inserted with the procedures similar to Figures 54 to 58, positioning the pair of anchors 144 into opposite sides of the loose sphincter 251. Figure 75 depicts tightening of the external sphincter 251 by pulling the suture 122 and pushing the plunger 109 against the proximal end of the suture lock 239 at the same time, as shown in Figure 61. As a result, the approximating device 273 restricts and narrows the circular external sphincter 251 by taking up the scarred 268 and loose tissue, as shown in Figure 75. The sutures 122 can then be knotted 125 and cut beneath the skin, as shown in Figures 62, 70 and 75. The suture 122, anchors 144 and lock 239 can be made with biodegradable materials.

Oozing from the sphincteric 251 muscle traumatized by insertions of needles 103 and suture anchors 144 can initiate permanent tissue adhesion, holding and keeping the sphincter 251 in the approximated position even after degradation of the suture 122 and the anchors 144.

- 5 The tips of most surgical needles are designed to cut as well as puncture into tissue. On the other hand, for delivering the approximating device 273 along a slender tissue, a tip without cutting edges, similar to a sewing needle shown in Figure 76, is preferred. The tip with non-cutting edges is more likely to advance within a tissue with longitudinally oriented fibers, especially accompany with rotation during advancement. The slender
- 10 tissue can be a tendon or a ligament with collagen bundles 270 formed lengthwise along the tissue. Figure 77 depicts the needle 103 with non-cutting edges being advanced along a ligament 138 using rotational motion to drill and split a path between collagen bundles 270. The needle 103 can also be made with flexible or shape memory material, such as
- 15 nickel-titanium alloy, to conform within the tendon or ligament 138. When the appropriate depth of the needle 103 is reached, both the distal and proximal anchors 144 can then be individually delivered with sleeves 220. To guide the rotational needle 103 into tissue, radiopaque, echogenic or other tracing agents can also be injected through a lumen 269, as shown in Figure 78.

- Uterine prolapse is commonly caused by sagging ligaments. The current treatment is
- 20 hysterectomy. Figure 79 indicates a cross-sectional view of uterine 161 supports. The cardinal ligament 253 provides for lateral support, sacrouterine ligament 254 for posterior support and fascia 255 for anterior support to the uterus 161.

- Similar to the hysterectomy procedure through the vagina 114 under general anesthesia, the muscles and ligaments are relaxed. The uterus 161 is pulled down from the
- 25 vagina 114 by a grasping device 259 to expose the cardinal 253 and sacrouterine 254 ligaments, as shown in Figure 80, with ovaries 256, fallopian tubes 258 and round ligaments 257 within the abdomen. Using various guiding and insertion techniques, the needle 103 is advanced along the ligament 253 or 254 to deliver the anchors 144, as shown in Figure 80. The sutures 122 are loaded with suture locks 239 and plungers 109.
- 30 The approximating devices 273 are then individually tightened by advancing the plungers 109 against the suture locks 239, while the sutures 122 are being pulled to plicate and shorten the ligament 253 and/or 254, as shown in Figure 81. In essence, the ligament 253

and/or 254 is folded, crinkled or bunched together under the tension of the approximating devices 273. As a result, the cervix 271 and the entire uterus 161 are lifted by the shortened cardinal 253 and/or sacrouterine 254 ligaments.

The shortened ligament can be permanently maintained to uphold the uterus 161. As the ligament 253 and/or 254 are traumatized by insertions of needles 103 and anchors 144, oozing from the traumatized tissue can initiate tissue adhesion to hold and keep the ligament 253 and/or 254 in the plicated position even after degradation of the suture 122 and the anchors 144. The plicated ligament 253 and/or 254 also undergo tissue remodeling, including collagen crosslinking, which may also result in permanent shortening of the ligament 253 and/or 254.

A modified procedure and a suture-gripping device are designed for fastening an anchor 144 within thin tissue. Figure 82 depicts partial insertion of the proximal anchor 144 of the approximating device 273 into a thin tissue 130. Figure 83 shows a prior art suture-gripping device 264, with juttred flaps 265 biting and resisting upward slippage of the suture 122. The suture-gripping device 264 loaded on the suture 122 is followed by the plunger 109, as indicated in Figure 84. The needle 103 and sleeve 220 are then withdrawn from tissue 130. Similar to the procedure depicted in Figure 61, the sutures 122 are pulled, and the plunger 109 is pushed against the suture gripping device 264 to draw the proximal anchor 144 into the tissue 130 and tighten the approximating device 273. Then, knots 125 are tied beneath the gripping device 264 to secure the sutures 122, as shown in Figure 85.

Accuracy of needle 103 insertion of the approximating device 273 can be improved with a guide 185, as shown in Figure 86. The guide 185 contains a track 262 for the needle 103 to slide along, an extendible arm 260 to align with the needle 103, and a pointer 261 to indicate the target site. In addition, measuring units on the arm 260 indicate depth of needle 103 penetration.

As mentioned, the traditional surgical treatment for urinary incontinence is to provide backboard support to the urethral posterior wall 151 by pulling the vagina 114 forward with sutures 122. The sutures 122 are then fastened onto the fascia or ligament in the abdominal wall, as indicated in Figures 17 and 18. The approximating device 273 can provide similar backboard support to the posterior wall 151 without any incision 157. Figure 87 depicts the vagina 114 is dilated with a retractor 196. The needle 103 is

inserted through the anterior wall of the retracted vagina 114, lateral to the bladder neck 112, through the fascia 255 or ligament into adipose tissue 272 above the pubic symphysis 115. The distal anchor 144 is then deployed within the adipose tissue 272 and the proximal anchor 155 within the vaginal 114 wall with the suture-gripping device 264. The
5 approximating device 273 is then tightened by pulling the suture 122 and pushing the plunger 109. The tightness of the plication can be seen through the urethra 101 with an endoscope 263. The suture 122 is then knotted 125 and cut, as shown in Figures 85 and 88. Figure 88 shows a minimally invasive approach to supporting the posterior-urethral wall 151 of the urethra 101 by pulling the vaginal 114 wall forward with approximating
10 devices 273. As mentioned, trauma from insertion of needles 103 and anchors 144 can lead to tissue adhesion, providing permanent posterior wall 151 support even after degradation of the suture 122, anchor 144 and gripping device 264.

It may also be possible to tighten the bladder-neck 112 and restrict the sphincteric region of the urethra 101 without involving the ligament or fascia 255 in the abdominal
15 wall. The needle 103 can be inserted lateral to the bladder neck 112 or the urethra 101, into the retropubic space 274, area between the pubic symphysis 115 and bladder/urethra 127/101, to deliver the distal anchor 144. The proximal anchors 144 are deployed as mentioned within the vaginal 114 wall. As the approximating devices 273 are tightened, the bladder neck 112 as well as the urethra 101 are sandwiched between the anterior 152
20 fascia and the vagina 114, as shown in Figure 89, to tighten the bladder neck 112 and treat sphincteric deficiency.

The most difficult step in installing the approximating device 273 is probably the guidance of the needle 103 safely and accurately into tissue. To maximize the benefit from the effort of needle 103 insertion, multiple pairs of approximating devices 273 can be
25 loaded or passed along the needle 103, as shown in Figure 90. With only a single needle 103 insertion, the approximating strength is greatly enhanced with multiple devices 273 installed, as shown in Figure 91.

The dynamics of anchor 144 pivoting or rotation responding to suture 122 tension is especially significant within thin tissue 130. From observation within transparent gel wax,
30 the initial movement of a crude prototype anchor 144 responding to suture 122 tension was in both pullout and lateral rotational directions. A similar result was obtained in meat. The suture 122 was not truly fastened until the prototype anchor 144 had rotated from the

insertion position to fastening or perpendicular position. Before the fastened position was achieved, the suture 122 could be pulled with some resistance. The pivotal or rotational efficiency of the anchor 144 can probably be described by the pullout distance of the pulled suture 122. In an experiment using pork and the crude prototype anchor 144, the pullout distance was about one and half lengths of the prototype anchor 144 before the anchor 144 was secured. Within thin tissue, the anchor 144 would be pulled out before reaching the fastened position. With modifications to the crude prototype anchor 144, rotational efficiency can be significantly improved.

The needle 103 can also contain an inner and outer sleeves 220. The sleeves 220 are stacked over each other, and both sleeves 220 capable of sliding over the needle 103, as shown in Figure 92. The lumen 104 of the distal anchor 144 fits over the distal portion of the needle 103, but too small to fit over the inner sleeve 220. The slightly larger lumen 104 of the proximal anchor 144 fits over the inner sleeve 220, but too small to fit over the outer sleeve 220. In essence, the inner sleeve 220 supports the distal anchor 144 and the outer sleeve 220 supports the proximal anchor 144, with both sleeves 220 and anchors 144 fit over the needle 103. Spearheading by the needle 103, the anchors 144 and sleeves 220 are punctured into tissue. Within a proper depth into the tissue, the inner sleeve 220 is held stationary while the needle 103 is partially withdrawn to disengage and deploy the distal anchor 144. Similarly, the outer sleeve 220 is held stationary while the needle 103 is fully withdrawn to deploy the proximal anchor 144.

The fin 134 can extend beyond the length of the body 275 and be made pointed to spearhead and expedite the rotation of the suture anchor 144, as shown in Figure 93. The side view of the pointed and extended fin 134 is more evident in Figure 94. The sharpened fin 134 helps lateral penetration into tissue 130. Extension of the fin 134 lengthens L_1 favors and expedites lateral rotation of the anchor 144. Even though L_1 is significantly lengthened, the suture holes 123 are still at or near the center of the platform 133 to prevent excessive rotation after reaching the fastened position.

Anchor 144 rotation begins with lateral tissue 130 penetration of the fin 134, followed by the proximal end of the body 275, then the platform 134 of the anchor 144. To ease tissue 130 penetration and expedite rotation, the proximal portion of the platform 133 is tapered and curved toward the fin 134, as shown in Figures 93 and 94. As the anchor 144 rotates, the curved platform 133 follows the fin 134 and smoothly lodges into the tissue

130. The tapered proximal end of the anchor 144 is supported by a shape-matching step 165 on the needle 103, as shown in Figure 94. The shape-matching contact between the anchor 144 and the step 165 also helps to minimize spinning of the anchor 144 around the delivering needle 103.

- 5 Location of the elastic curvature of the anchor 144 can also affect the rotational efficiency. The curvature near the proximal end of the anchor 144 is more likely to have better rotational efficiency than the efficiency of the curvature situated near the distal end of the anchor 144.

A wide range of materials can be used to fabricate the suture anchor 144.

- 10 Biocompatible polymers, such as polypropylene, polyethylene, poly-ether-ether-ketone, acetal resin, polysulfone and polycarbonate, are possible candidates. For biodegradable capability, the anchor 144 can be made with polylactate, polyglycolic, poly-lactide-co-glycolide, polycaprolactone, trimethylene carbonate or combinations of these materials. Many of these degradable polymers are in US FDA approved products. Other degradable
- 15 polymers, such as polydioxanone, polyanhydride, trimethylene carbonate, poly-beta-hydroxybutyrate, polyhydroxyvalerate, poly-gama-ethyl-glutamate, poly-DTH-iminocarbonate, poly-bisphenol-A-iminocarbonate, poly-ortho-ester, polycyanoacrylate and polyphosphazene can also be used. Nickel-titanium alloy, spring-tempered stainless steel, titanium, stainless steel or other metallic material provides strength and durability.

- 20 The anchor 144 can also be coated with biocompatible polymers, such as polyurethane, polytetrafluoroethylene, silicon, ultra high molecular weight polyethylene or other material. For additional biological and surgical benefits, the anchor 144 can also be coated with lubricants, growth factors, nutrients, buffering agents, collagen, hydroxyapatite, analgesics, sealants, blood clotting agents, antibiotics, radiopaque or
- 25 echogenic agents. All materials should be able to withstand sterilization by gamma, electron beam, autoclave, ETO, plasma or UV light to prevent infection.

- The stepped needle 103 and sleeve 220 can be made with stainless steel, titanium, nickel titanium other metal or alloy. The stepped needle 103 and sleeve 220 can be coated with lubricant, blood clotting, radiopaque or echogenic agents. For hard-to-reach surgical
- 30 sites, the stepped needle 103 can be made curved to gain accessibility for the surgeon. To accommodate the curvature of the stepped needle 103, the sleeve 220 can also be made with elastic material, such as nickel titanium, polypropylene, polyethylene or other flexible

material. The stepped needle 103 and sleeve 220 can also be coated with lubricant, antibiotic, radiopaque or echogenic agents.

The suture 122 can be permanent or biodegradable, braided or monofilament. The suture 122 can also be metallic for strength and durability.

5 In summary, the anchor 144 is designed for partial thickness or full thickness suture 122 anchoring and is delivered with the stepped needle 103. Deployment of the anchor 144 can be as simple as inserting and withdrawing the stepped needle 103 in and from tissue. The sleeve 220 sliding over the stepped or a smooth needle 103 can be helpful in deploying the anchor 144 and manipulating tissue. The curvature of the anchor 144
10 promotes initial anchor 144 rotation within tissue when tension is applied to the suture 122. The fin 134 is designed to (1) dislodge the anchor 144, (2) enhance initial rotation of the anchor 144, and (3) stabilize the anchor 144 during rotation. The platform 133, especially fortified with bend stops 155, is designed to increase the anchoring strength within tissue. When multiple anchors 144 are delivered in series into tissue, as the suture
15 122 is pulled, the anchors 144 draw close to each other to plicate or approximate the pierced tissue.

It is to be understood that the present invention is by no means limited to the particular constructions disclosed herein and/or shown in the drawings, but also includes any other modification, changes or equivalents within the scope of the claims. Many features have
20 been listed with particular configurations, curvatures, options, and embodiments. Any one or more of the features described may be added to or combined with any of the other embodiments or other standard devices to create alternate combinations and embodiments.

It should be clear to one skilled in the art that the current embodiments, materials, constructions, methods, tissues or incision sites are not the only uses for which the
25 invention may be used. It has been foreseen that the anchor 144 and the stepped needle 103 can be applied in other surgical and non-surgical purposes. Different materials, constructions, methods or designs for the anchor 144, stepped needle 103 or the sleeve 220 can be substituted and used. Nothing in the preceding description should be taken to limit the scope of the present invention. The full scope of the invention is to be
30 determined by the appended claims.

What is claimed is:

1. A suture anchor deployable with a suture anchor delivery device having a needle, the suture anchor comprising:
 - a suture anchor body having a longitudinal axis and formed of an elastic material, said suture anchor body having a straightened position and a curved position,
 - a passage extending through said suture anchor along said longitudinal axis, said passage sized and configured for the needle of the suture anchor delivery device to pass therethrough,
 - a suture opening sized and configured to received a suture, said suture opening passing through a portion of said suture anchor,
 - a guiding platform attached to one side of said suture anchor body, wherein said suture body is resiliently straightened into said straightened position when the needle of said suture anchor delivery device is located within said passage,
 - and wherein when the needle is removed, said suture anchor body resumes said curved position.
2. The suture anchor of claim 1, wherein said guiding platform is generally flat.
3. The suture anchor of claim 1, wherein said suture opening passes through said platform.
4. The suture anchor of claim 3, wherein said platform has a protrusion and said suture opening passes through said protrusion.
5. The suture anchor of claim 3, further comprising a second suture opening passing through said platform.
6. The suture anchor of claim 5, wherein one of said suture openings is located on a left side of said platform and the other suture opening is located on a right side of said platform.
7. The suture anchor of claim 1, wherein said platform is located on a concave side when said suture anchor is in said curved position.
8. The suture anchor of claim 1, wherein said platform is located on a convex side when said suture anchor is in said curved position.
9. The suture anchor of claim 1, further comprising a groove located on a bottom surface of said platform, and wherein said groove is closed when said suture anchor is in said curved position.
10. The suture anchor of claim 9, wherein said groove is V-shaped.

11. The suture anchor of claim 1, wherein said platform is near a middle portion of said suture anchor.
12. The suture anchor of claim 1, wherein said platform extends along at least a majority of a length of said suture anchor body.
13. The suture anchor of claim 1, wherein said platform extends along approximately three quarters of a length of said suture anchor body.
14. The suture anchor of claim 1, wherein a longitudinal axis of said platform runs generally parallel to said longitudinal axis of said suture anchor body.
15. The suture anchor of claim 1, wherein a distal end of said platform is tapered.
16. The suture anchor of claim 1, wherein a proximal end of said platform is tapered.
17. The suture anchor of claim 1, wherein said platform is tapered at both proximal and distal ends.
18. The suture anchor of claim 1, wherein said platform is mounted generally tangentially to said suture anchor body.
19. The suture anchor of claim 1, wherein said platform is oblong.
20. The suture anchor of claim 1, wherein a proximal end of said platform curves around a proximal end of said suture anchor body, thereby covering the proximal end of said suture anchor body.
21. A suture anchor deployable with a suture anchor delivery device having a needle, the suture anchor comprising:
- a suture anchor body having a longitudinal axis and formed of an elastic material, said suture anchor body having a straightened position and a curved position,
 - a passage extending through said suture anchor along said longitudinal axis, said passage sized and configured for the needle of the suture anchor delivery device to pass therethrough,
 - a suture opening sized and configured to received a suture, said suture opening passing through a portion of said suture anchor,
 - a guiding fin attached to one side of said suture anchor body, wherein said suture anchor body is resiliently straightened into said straightened position when the needle of said suture anchor delivery device is located within said passage,
 - and wherein when the needle is removed, said suture anchor body resumes said curved position.
22. The suture anchor of claim 21, wherein said fin extends generally perpendicular from said suture anchor body.

23. The suture anchor of claim 21, wherein said fin is located proximate said proximal end of said suture anchor body.
- 5 24. The suture anchor of claim 21, wherein said fin is tapered such that a proximal end of the said fin is larger than a distal end of said fin.
25. The suture anchor of claim 21, wherein said fin is located on a concave side when said suture anchor is in said curved position.
- 10 26. The suture anchor of claim 21, wherein said fin is located on a convex side when said suture anchor is in said curved position.
27. The suture anchor of claim 21, wherein a proximal end of said fin is angled.
- 15 28. The suture anchor of claim 21, wherein a proximal end of said fin is angled to match a tapered distal step of the needle.
29. The suture anchor of claim 21, wherein said fin is extending outward from a middle portion of said suture anchor body and wherein said suture opening extends therethrough.
- 20 30. The suture anchor of claim 21, wherein said suture opening is located opposite said fin.
31. The suture anchor of claim 21, wherein said fin has a pointed proximal tip that extends beyond an end of said suture anchor body.
- 25 32. A suture anchor deployable with a suture anchor delivery device having a needle, the suture anchor comprising:
a suture anchor body having a longitudinal axis,
30 a passage extending through said suture anchor along said longitudinal axis, said passage sized and configured for the needle of the suture anchor delivery device to pass therethrough,
a suture opening sized and configured to received a suture, said suture opening passing through a portion of said suture anchor,
35 a guiding fin attached to a first side of said suture anchor body,
a guiding platform attached a second side of said suture anchor body.
33. The suture anchor of claim 32, wherein said guiding fin extends generally perpendicular to said guiding platform.
- 40 34. The suture anchor of claim 32, wherein a proximal end of said platform curves around a proximal end of said suture anchor body, thereby covering the proximal end of said suture anchor body and wherein said fin has a pointed proximal tip that extends beyond an end of said suture anchor body and said platform.
- 45 35. The suture anchor of claim 32, wherein said suture anchor is formed of an elastic material.

36. The suture anchor of claim 35, wherein said suture anchor has a straightened position and a curved position, and wherein said suture anchor may be held in said straightened position by the needle, when the needle is located within said passage, and when said needle is removed, said suture anchor resumes said curved position.
- 5 37. The suture anchor of claim 1, 21 or 32, wherein said suture anchor is formed of a material chosen from the group of materials consisting of polypropylene, polyethylene, poly-ether-ether-ketone, acetal resin, polysulfone and polycarbonate.
- 10 38. The suture anchor of claim 1, 21 or 32, wherein said suture anchor is biodegradable.
39. The suture anchor of claim 1, 21 or 32, wherein said suture anchor is formed of a material chosen from the group of materials consisting of polylactate, polyglycolic, poly-lactide-co-glycolide, polycaprolactone, and trimethylene carbonate.
- 15 40. The suture anchor of claim 1, 21 or 32, further comprising a coating on said suture anchor.
41. The suture anchor of claim 1, 21 or 32, further comprising a coating on said suture anchor, said coating chosen from the group of coatings consisting of lubricants, growth factors, nutrients, buffering agents, collagen, hydroxyapatite, analgesics, sealants, blood clotting agents, antibiotics, radiopaque agents and echogenic agents.
- 20 42. The suture anchor of claim 1, 21 or 32, further comprising a coating of a biocompatible polymer.
- 25 43. The suture anchor of claim 1, 21 or 32, further comprising a coating of chosen from the group of coatings consisting of polyurethane, polytetrafluoroethylene, silicon, and ultra high molecular weight polyethylene.
- 30 44. The suture anchor of claim 1, 21 or 32, wherein said suture anchor is formed of a material chosen from the group of material consisting of polypropylene, polyethylene, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate, polylactate, polyglycolic, poly-lactide-co-glycolide, polycaprolactone, trimethylene carbonate, polydioxanone, polyanhydride, trimethylene carbonate, poly-beta-hydroxybutyrate, polyhydroxyvalerate, poly-gama-ethyl-glutamate, poly-DTH-iminocarbonate, poly-bisphenol-A-iminocarbonate, poly-ortho-ester, polycyanoacrylate, polyphosphazene, nickel-titanium alloy, spring tempered stainless steel, titanium, stainless steel and metallic material.
- 35 45. The suture anchor of claim 1, 21 or 32, further comprising a second suture anchor and a suture threaded through said suture opening and through a second suture opening extending through a body of said second suture anchor.
- 40 46. A suture anchor delivery system, comprising:
the suture anchor of claim 1, 21 or 36,
- 45

a needle having a step dividing said needle into a proximal portion and a distal portion, said distal portion being sized and configured to fit within said passage, said proximal portion having a larger diameter, wherein, when said needle is located within said passage, said needle holds said suture anchor in said straightened position.

47. The suture anchor delivery system of claim 46, wherein a proximal end of said suture anchor body rests against said step when said needle is located within said passage.

48. The suture anchor delivery system of claim 46, wherein a sharp distal end of said needle protrudes from a distal end of said passage.

49. The suture anchor delivery system of claim 46, further comprising a second step in said needle and a second suture anchor.

50. The suture anchor delivery system of claim 49, wherein said suture passing through both of said suture anchors.

51. A method for delivering a suture anchor within tissue of a patient, the method comprising the steps of:

- (a) puncturing the tissue with a needle, carrying a suture anchor;
- (b) removing the needle from the suture anchor;
- (c) and pulling a suture connected to the suture anchor causing a fin on the suture anchor to snag the surrounding tissue, thereby causing said suture anchor to rotate within tissue.

52. A method for delivering a suture anchor within tissue of a patient, the method comprising the steps of:

- (a) puncturing the tissue with a needle carrying a suture anchor;
- (b) removing the needle from the suture anchor, thereby allowing the suture anchor to resume its curved configuration;
- (c) and pulling a suture connected to the suture anchor causing a fin on the suture anchor to snag the surrounding tissue, thereby causing said suture anchor to rotate within tissue.

53. The method of claim 51 or 52 further comprising the step of:

- (d) holding the suture anchor in the tissue with a sleeve located around the needle during step (b).

54. The method of claim 51 or 52 used to treat urinary incontinence, the method further comprising the steps of:

- (d) identifying the location of the urethra;
- (e) inserting the needle into the anterior wall of a vagina of the patient lateral to the urethra during step (a);
- (f) repeating steps (a) thru (e) until a wall of the vagina is repositioned;
- (g) and tying the sutures, thereby supporting the urethra with the repositioned wall of the vagina.

55. The method of claim 51 or 52 used to treat uterine prolapse, the method further comprising the steps of:

- (d) repositioning the uterus;
- (e) fastening the repositioned uterus with steps (a) thru (c);
- 5 (f) and repeating steps (a) thru (c) until the uterus is secure.

56. The method of claim 51 or 52 used to reattach ligament onto bone, the method further comprising the steps of:

- (d) repositioning a torn ligament over bone;
- 10 (e) repeating steps (a) thru (c) until the ligament is secure;
- (f) tying the suture;
- (g) and allowing the ligament to heal over the bone.

57. The method of claim 56, wherein the bone is cancellous.

15

58. The method of claim 51 or 52 used to treat a bulging intervertebral disc, the method further comprising the steps of:

- (d) inserting the needle into the bulging disc in step (a);
- (e) pushing the suture anchor out an opposite side of the bulging disc;
- 20 (f) threading a disc compressing device onto the suture;
- (g) pulling and tying the suture, thereby compressing the bulging disc between the suture anchor and the disc compressing device.

59. The method of claim 58, wherein step (e) is performed by using a sleeve located around the needle to push the suture anchor.

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60. The method of claim 51 or 52, wherein step (b) is performed by the fin on the suture anchor snagging on the tissue, thereby holding the suture anchor in the tissue while the needle is withdrawn from the suture anchor.

30

61. The method of claim 60, wherein a second suture anchor is located on the needle and the suture passes through the second suture anchor and further comprising the steps of:

- (d) removing the needle from the second suture anchor;
- (e) allowing the second suture anchor to resume a curved configuration;
- 35 (f) pulling on the suture to cause the second suture anchor to rotate within the surrounding tissue;
- (g) and pulling the suture further to draw together the tissue proximate the first suture anchor and the tissue proximate the second suture anchor.

62. The method of claim 61, wherein the first suture anchor is located distal to said second suture anchor.

40

63. The method of claim 61 used to repair a loose anal sphincter, wherein in step (a), the tissue is both sides of the loose anal sphincter and step (g) narrows the sphincter.

45

64. The method of claim 61 used to shorten a ligament, wherein in step (a), the tissue is the ligament and step (g) shortens the ligament.

65. The method of claim 64, further comprising the step of repeating steps (a) thru (g) until the ligament is sufficiently shortened.
- 5 66. The method of claim 61 used for treating urinary incontinence, wherein in step (a), the needle passes through the vagina and into the abdominal fascia or ligament and step (g) moves a wall of the vagina to support a urethral wall.
- 10 67. The method of claim 66, further comprising the step of repeating steps (a) thru (g) until the urethral wall is supported sufficiently to alleviate the urinary incontinence.
68. The method of claim 61, wherein a second pair of suture anchors with a second suture is located on the needle and is deployed.
- 15 69. The method of claim 51 or 52, wherein step (b) is performed by a sleeve located around the needle holding the suture anchor in the tissue while the needle is withdrawn from the suture anchor.
- 20 70. The method of claim 69, wherein a second suture anchor is located on the needle and the suture passes through the second suture anchor and further comprising the steps of:
 (d) removing the needle from the second suture anchor;
 (e) allowing the second suture anchor to resume a curved configuration;
 (f) pulling on the suture to cause the second suture anchor to rotate within the surrounding tissue;
25 (g) and pulling the suture further to draw together the tissue proximate the first suture anchor and the tissue proximate the second suture anchor.
71. The method of claim 70, wherein step (d) is performed by the fin on the second suture anchor snagging on the tissue, thereby holding the second suture anchor in the tissue while the needle is withdrawn from the second suture anchor.
- 30 72. The method of claim 70, wherein step (d) is performed by the sleeve located around the needle holding the second suture anchor in the tissue while the needle is withdrawn from the second suture anchor.
- 35 73. The method of claim 70, wherein the first suture anchor is located distal to said second suture anchor.
74. The method of claim 70 used to repair a loose anal sphincter, wherein in step (a), the tissue is both sides of the loose anal sphincter and step (g) narrows the sphincter.
- 40 75. The method of claim 70 used to shorten a ligament, wherein in step (a), the tissue is the ligament and step (g) shortens the ligament.
- 45 76. The method of claim 75, further comprising the step of repeating steps (a) thru (g) until the ligament is sufficiently shortened.

77. The method of claim 70 used for treating urinary incontinence, wherein in step (a), the needle passes through the vagina and into the abdominal fascia or ligament and step (g) moves a wall of the vagina to support a urethral wall.

- 5 78. The method of claim 77, further comprising the step of repeating steps (a) thru (g) until the urethral wall is supported sufficiently to alleviate the urinary incontinence.

79. The method of claim 70, wherein a second pair of suture anchors with a second suture is located on the needle and is deployed.

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80. A suture anchor delivery device, comprising:

a needle,

a first sleeve located around said needle

and a second sleeve located around said needle and said first sleeve.

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81. The suture anchor delivery device of claim 80, further comprising a first suture anchor having a first passage extending therethrough, said first passage sized to receive said needle and sized too small to receive said first sleeve, and further comprising a second suture anchor having a second passage extending therethrough, said second passage sized to receive said first sleeve and sized too small to receive said second sleeve.

20

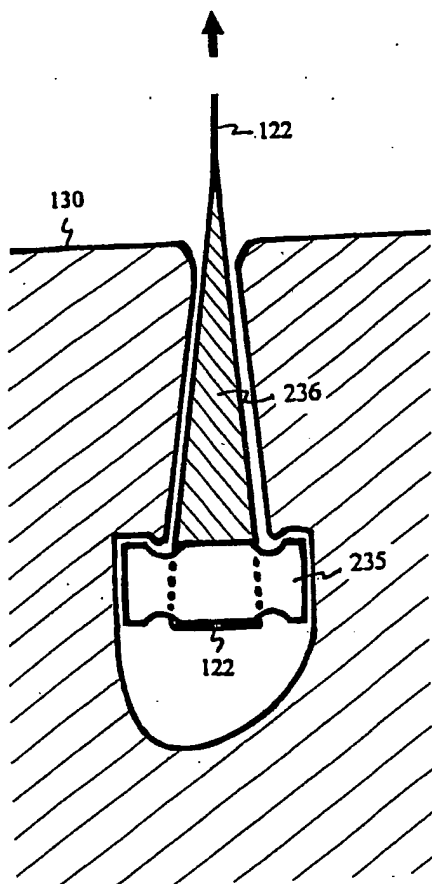
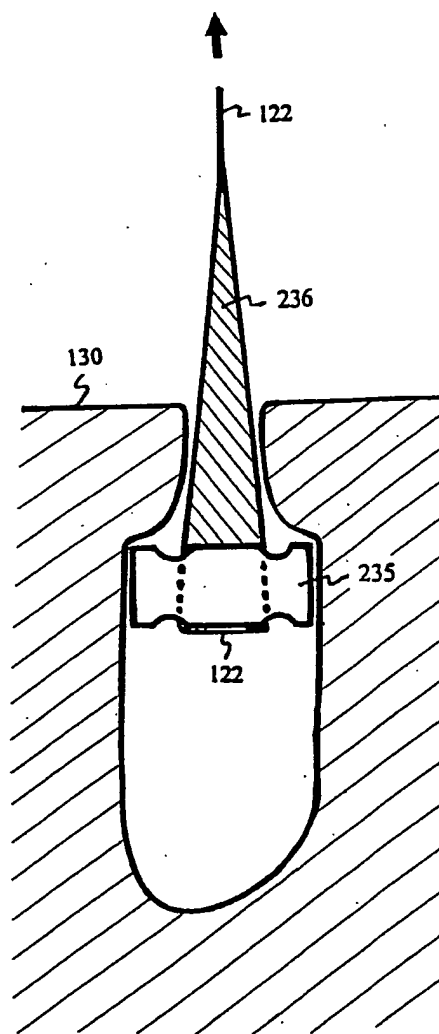


Figure 1
Prior Art

Figure 2
Prior Art



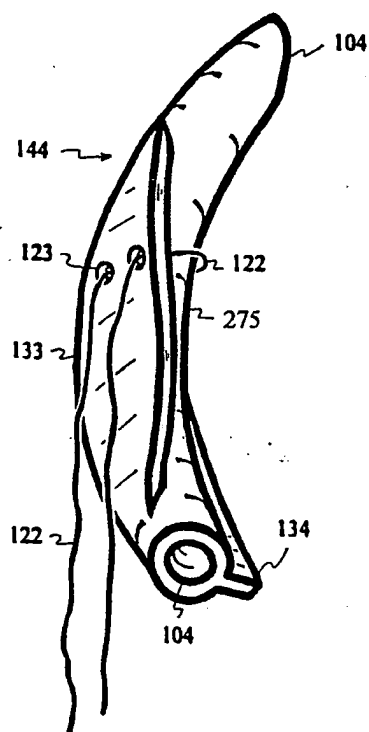


Figure 3

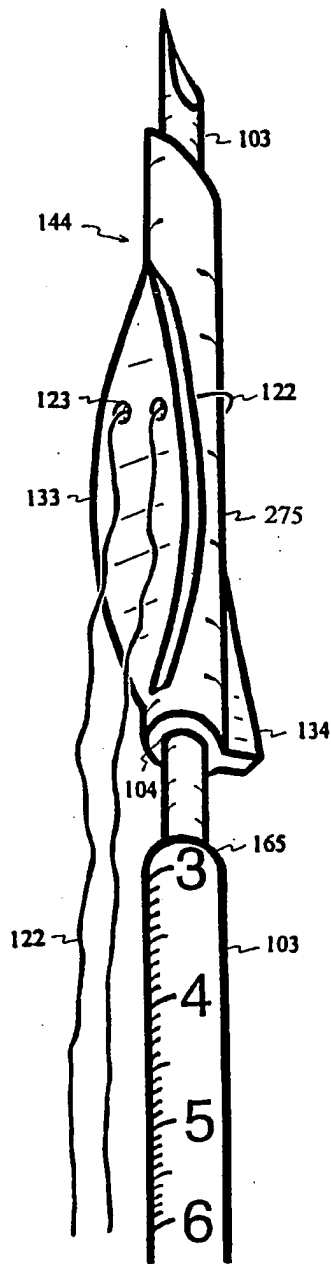


Figure 4

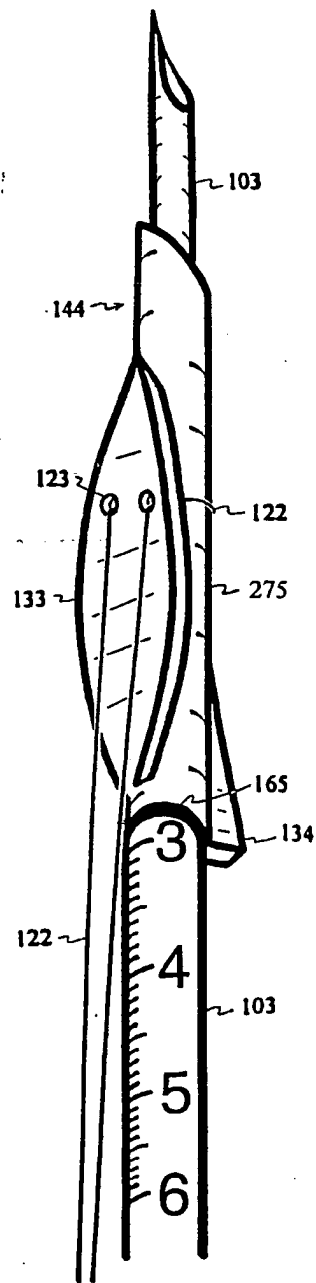


Figure 5

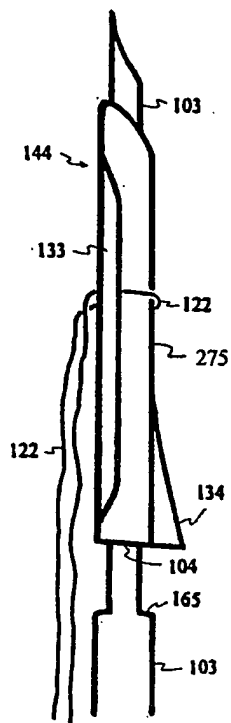


Figure 6

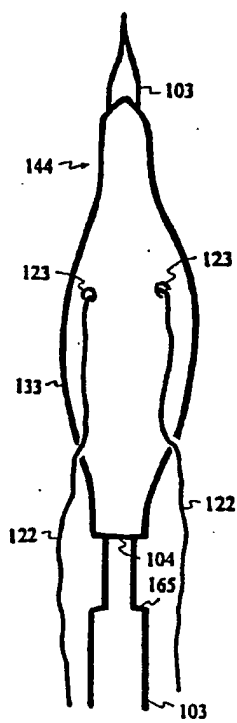


Figure 7

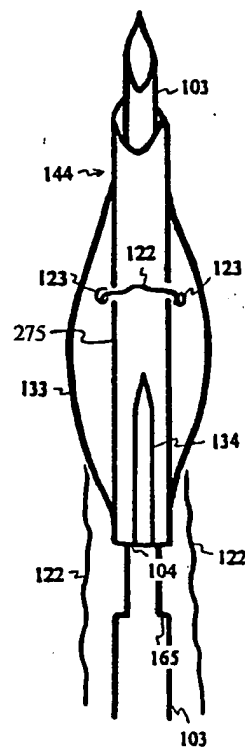


Figure 8

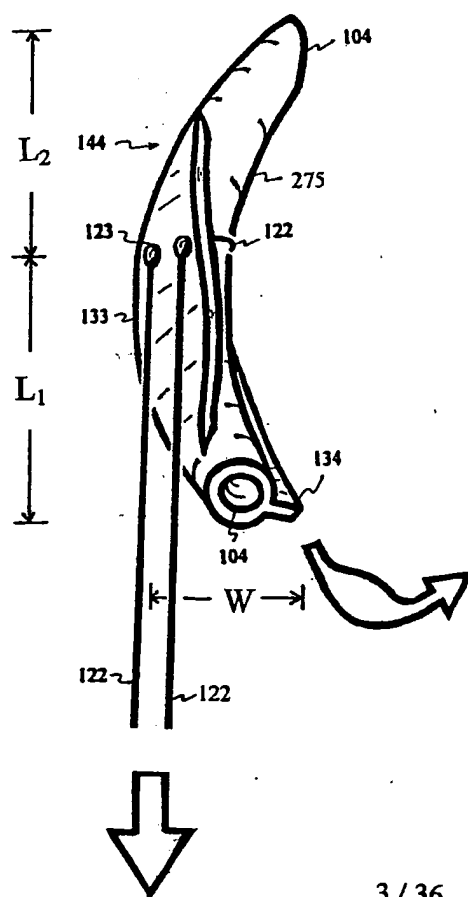


Figure 9

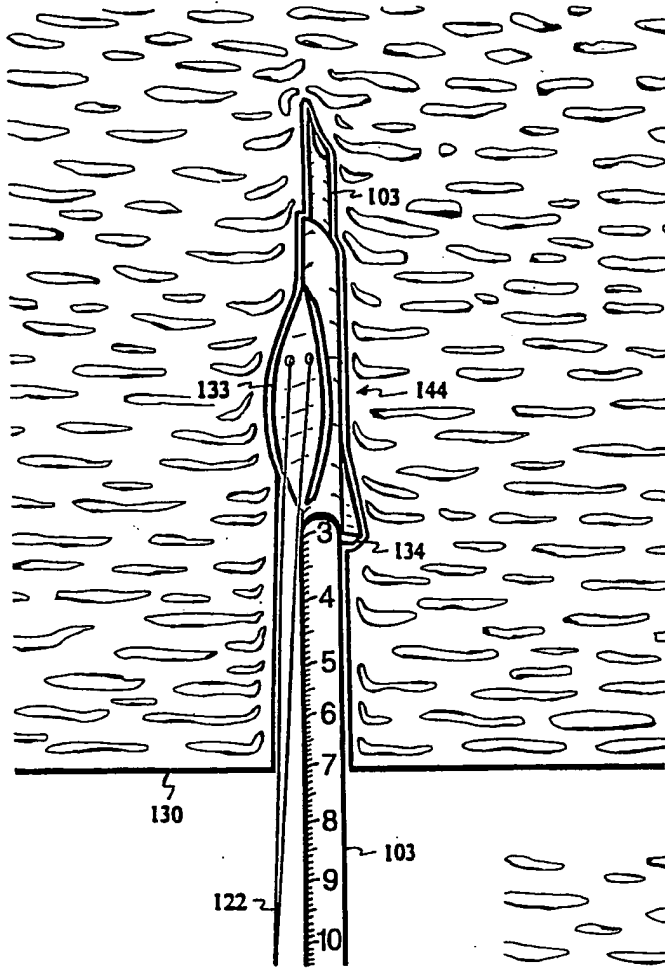


Figure 10

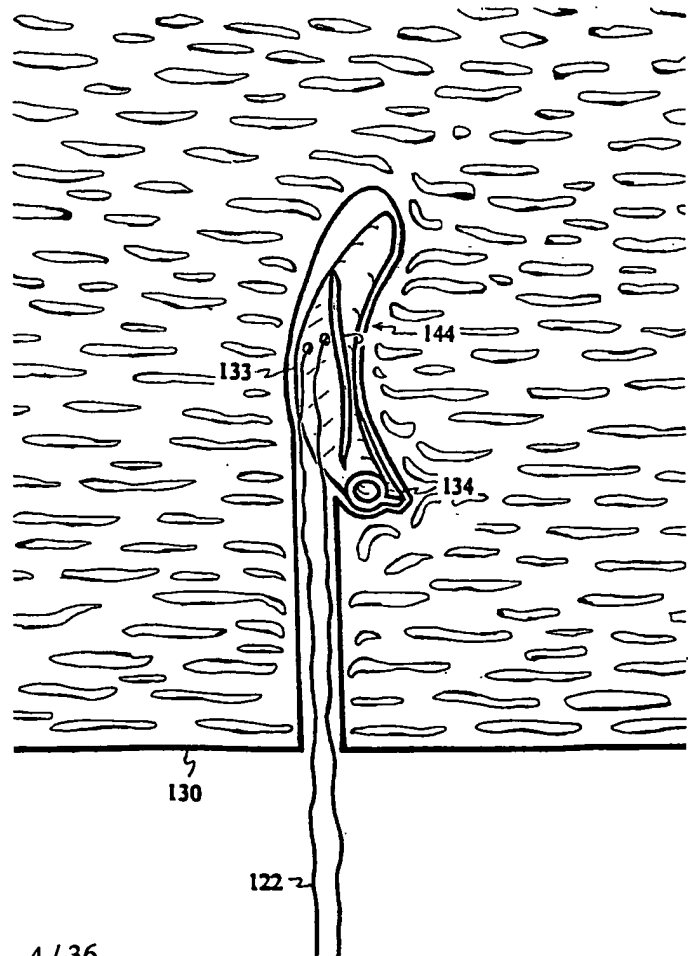


Figure 11

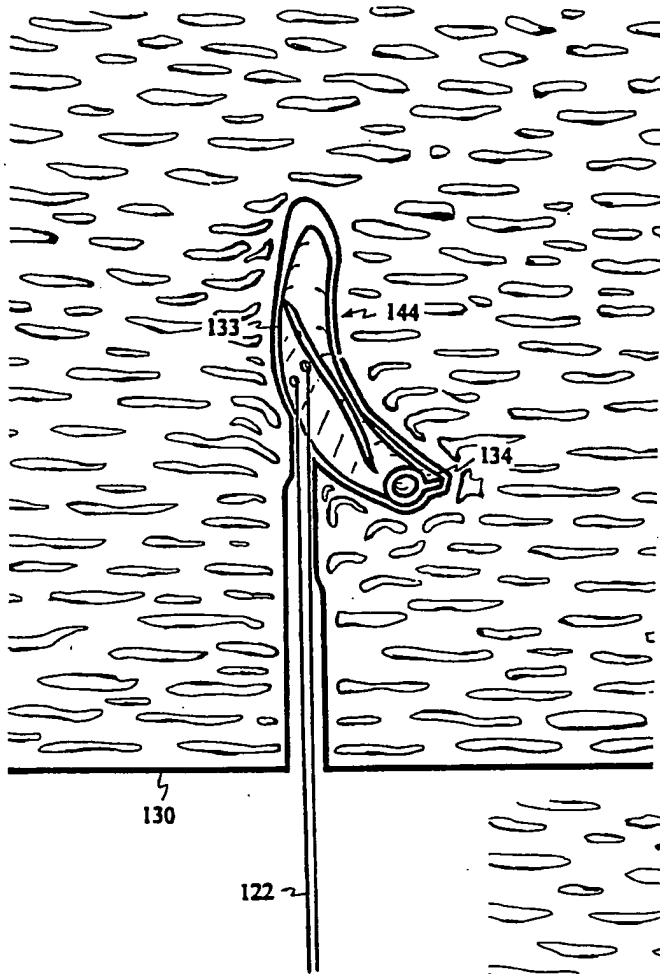
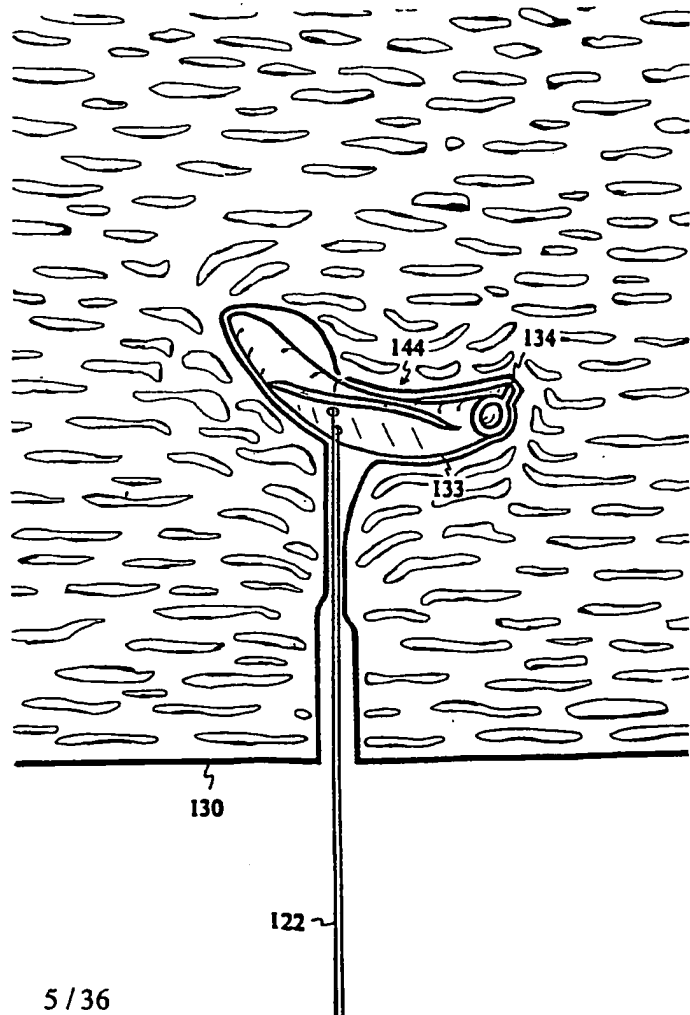


Figure 12

Figure 13



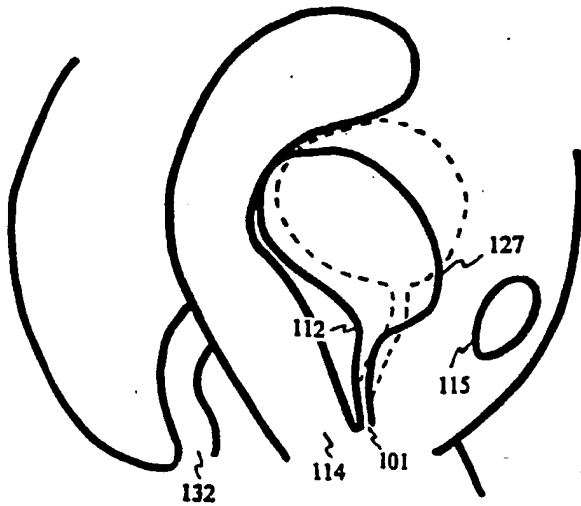


Figure 14

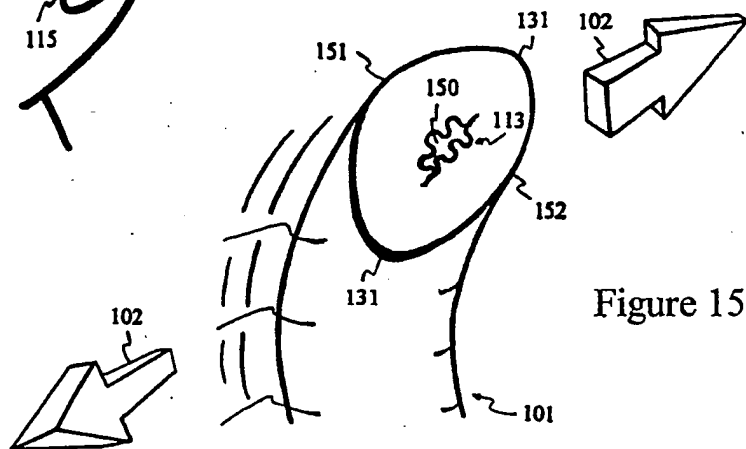


Figure 15

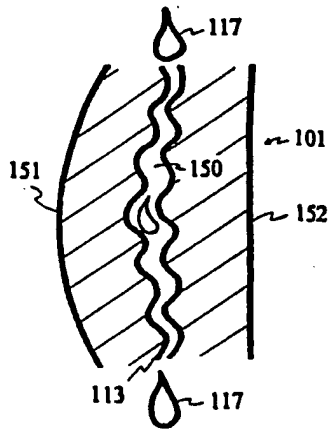


Figure 16

Figure 17
Prior Art

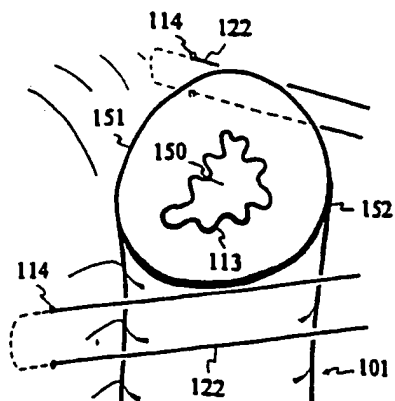
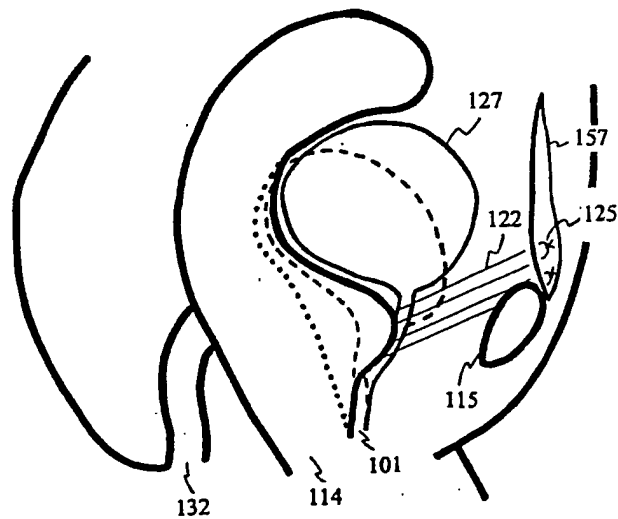


Figure 18
Prior Art

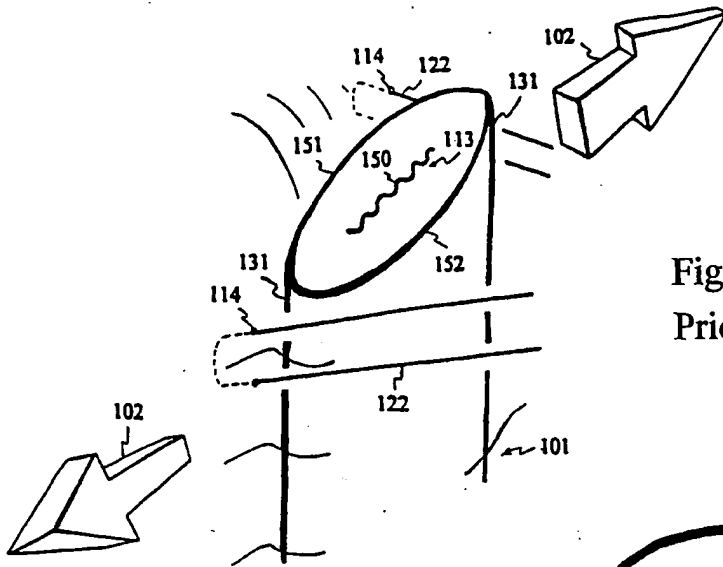


Figure 19
Prior Art

Figure 20

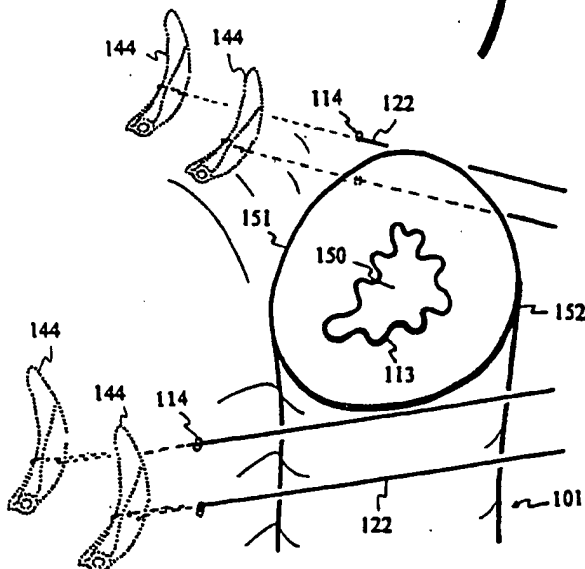
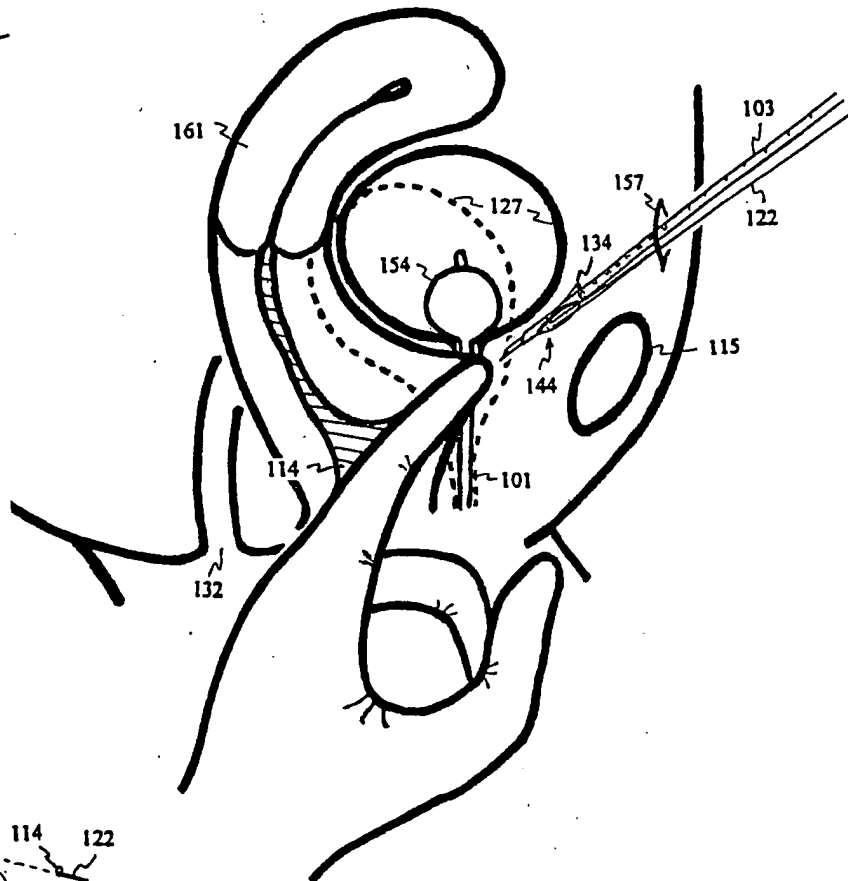


Figure 21

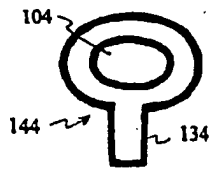


Figure 22

Figure 23

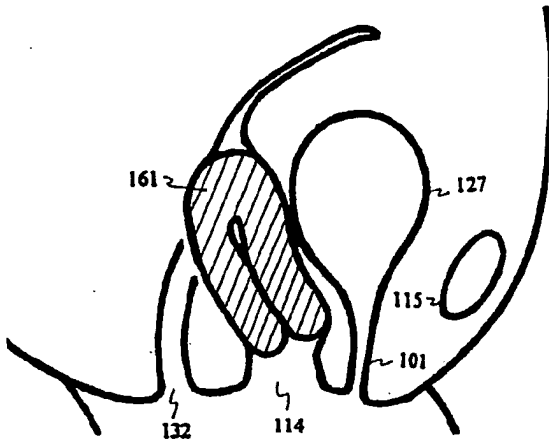
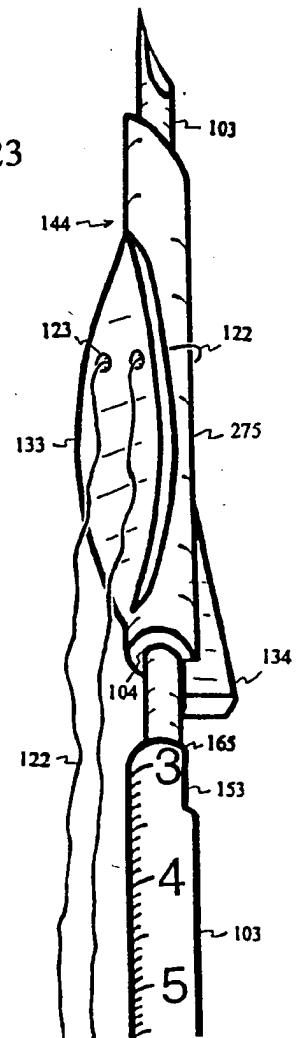


Figure 24

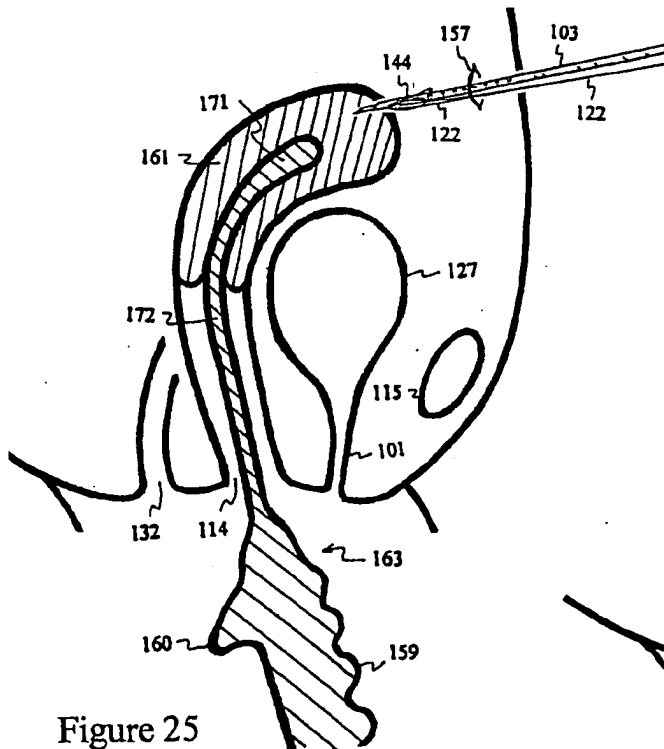


Figure 25

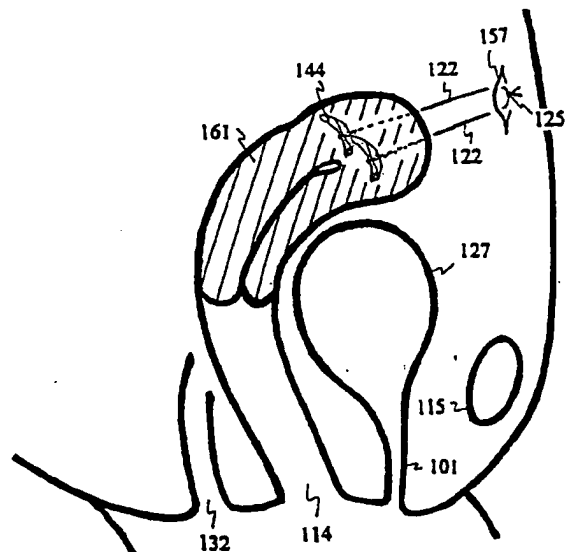


Figure 26

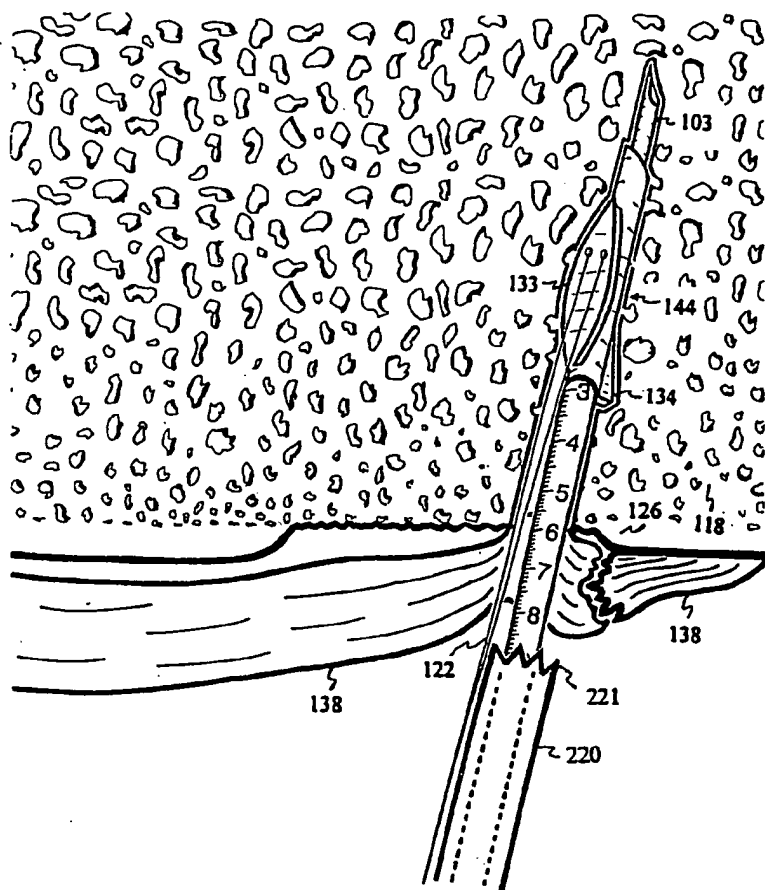
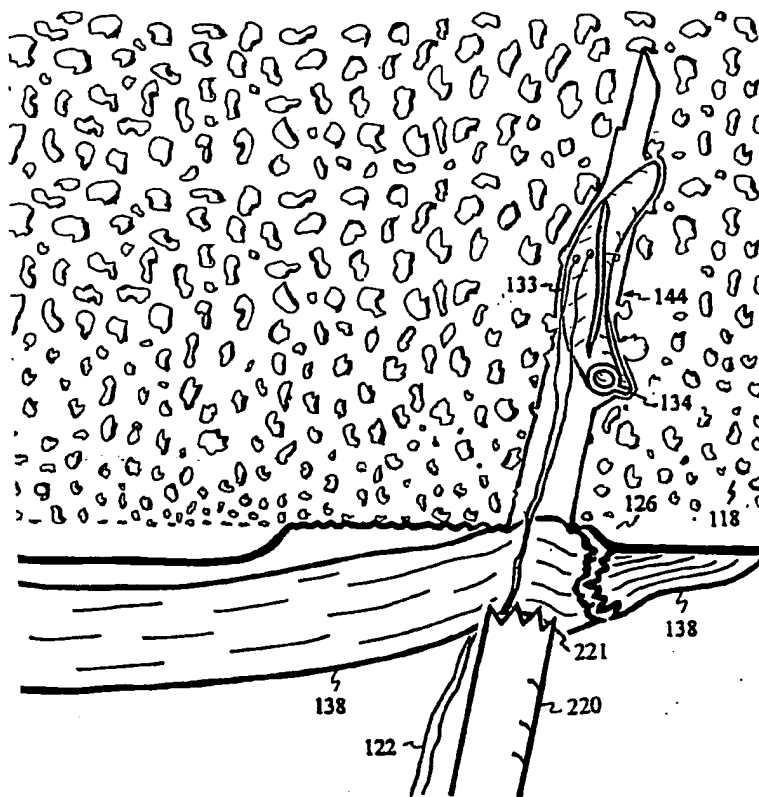


Figure 27

Figure 28



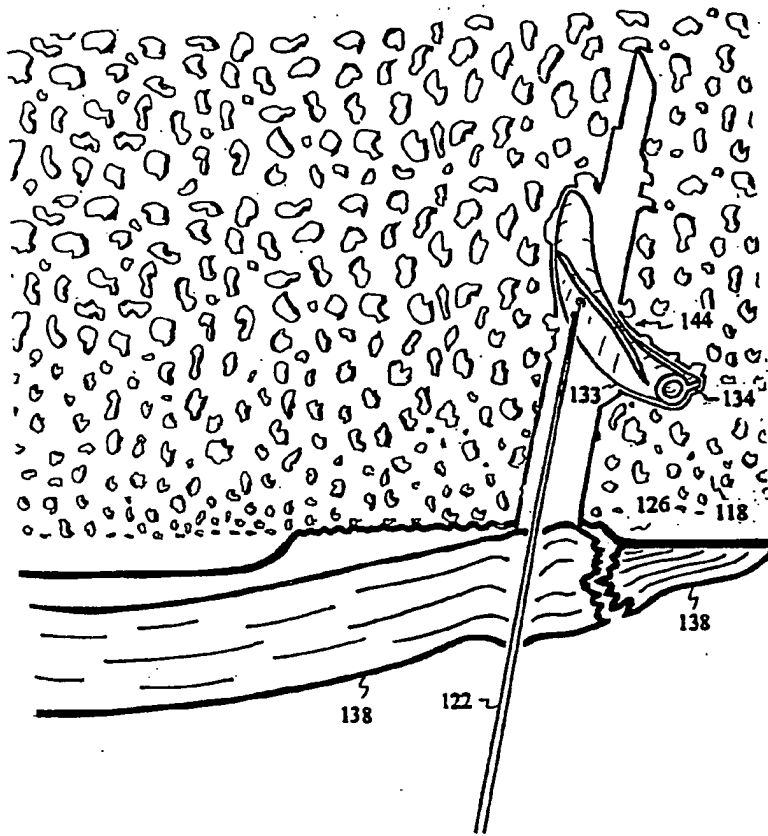


Figure 29

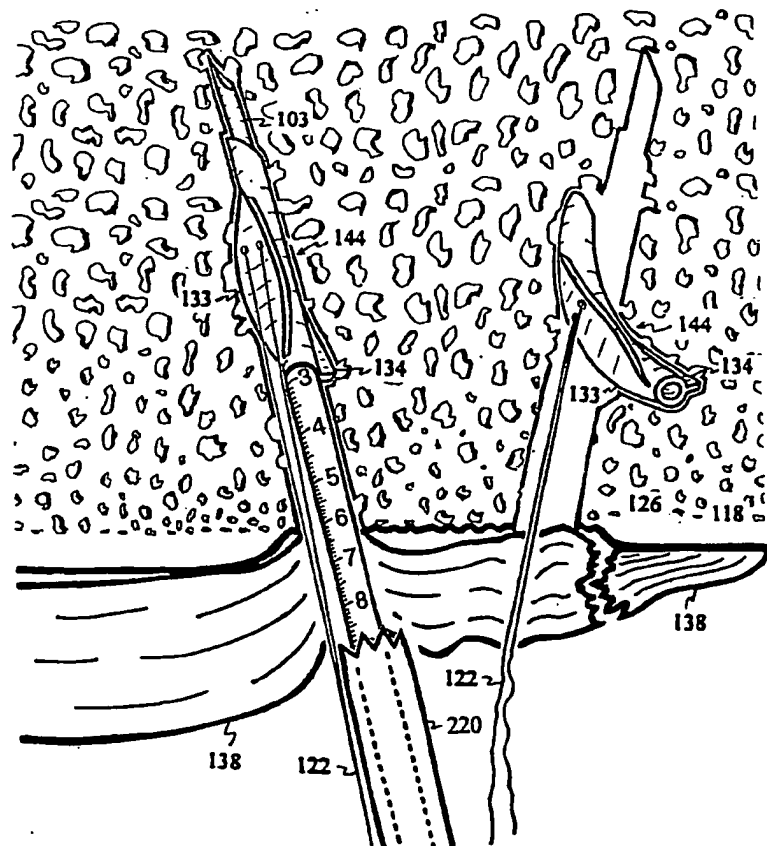


Figure 30

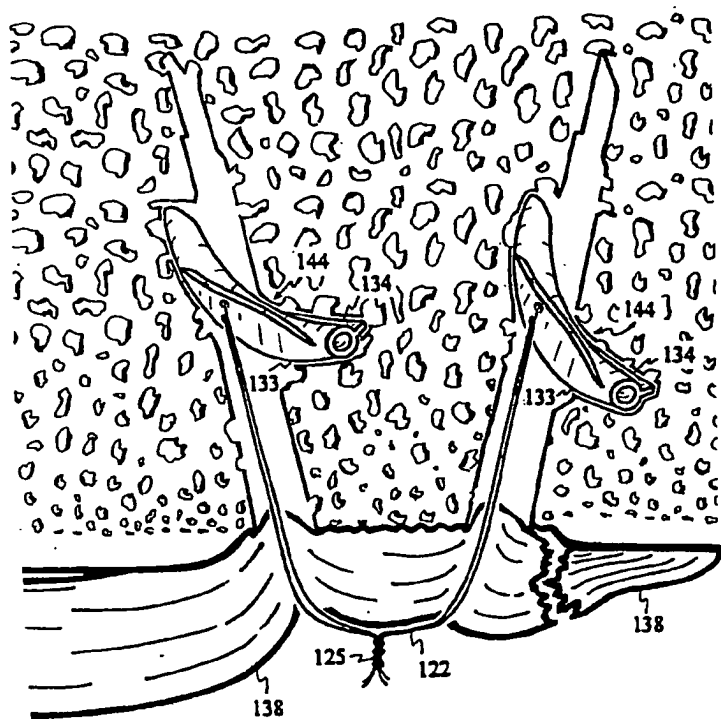


Figure 31

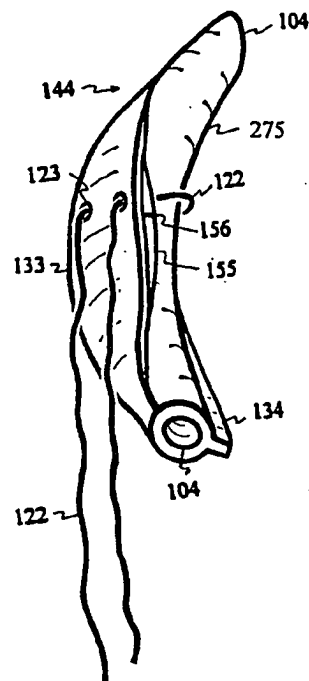


Figure 32

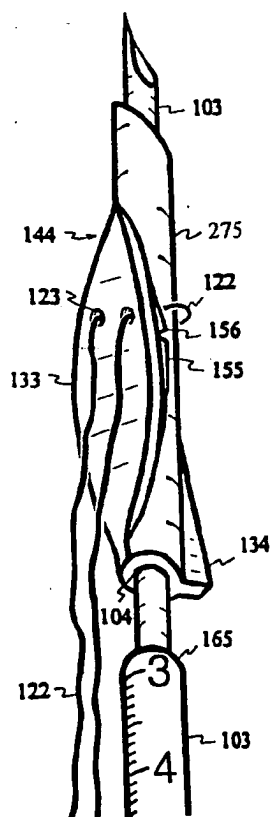


Figure 33

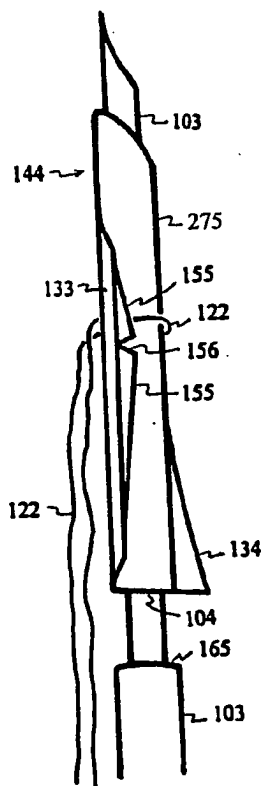


Figure 34

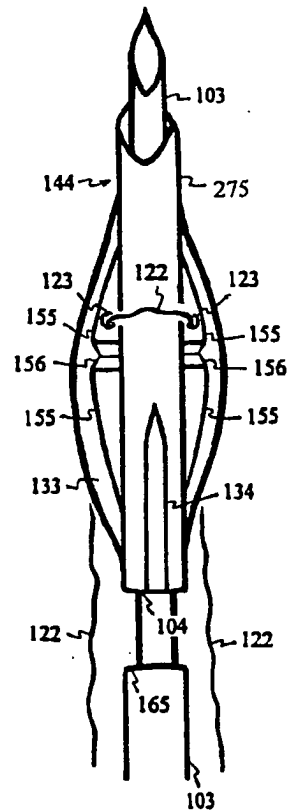


Figure 35

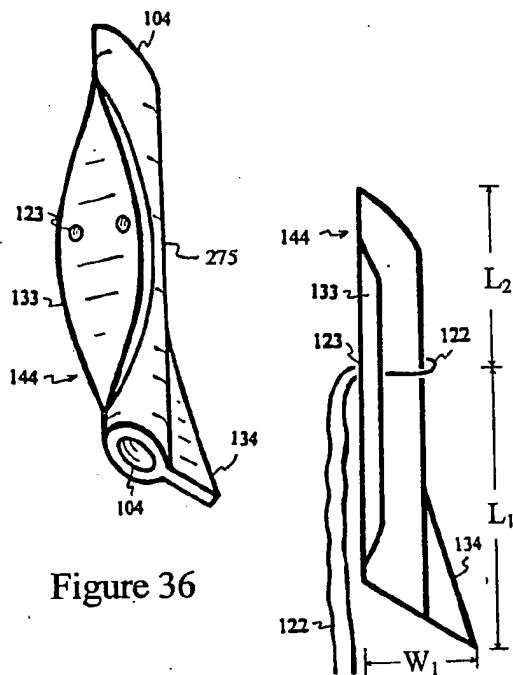


Figure 36

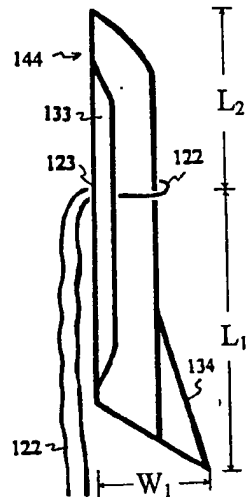


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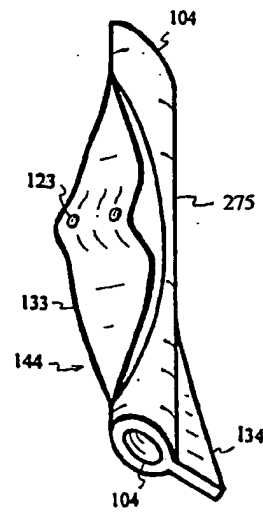


Figure 38

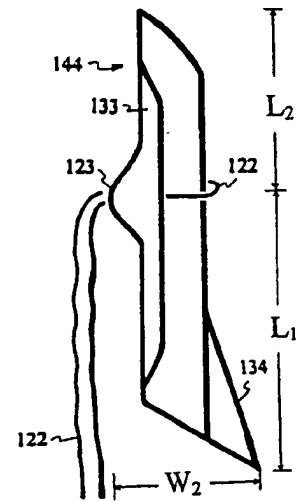


Figure 39

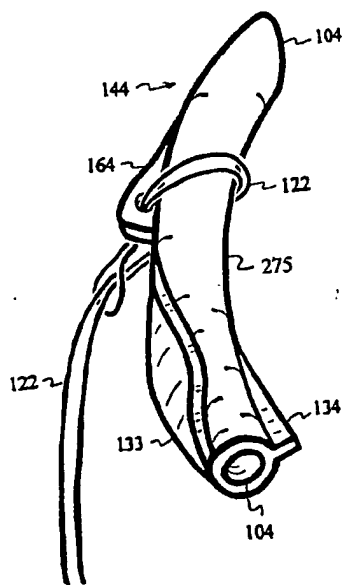


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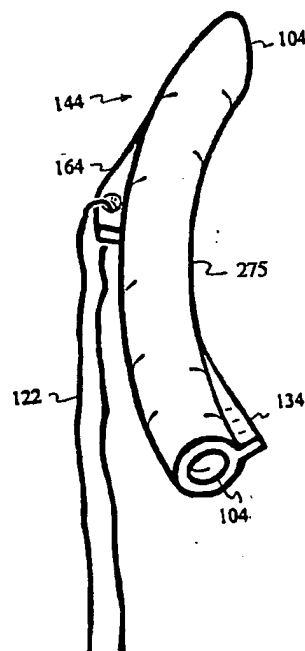


Figure 41

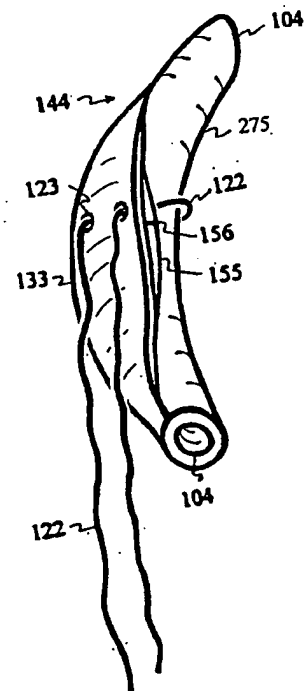


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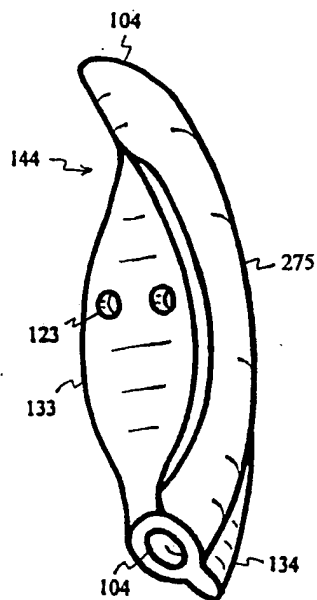


Figure 43

Figure 44

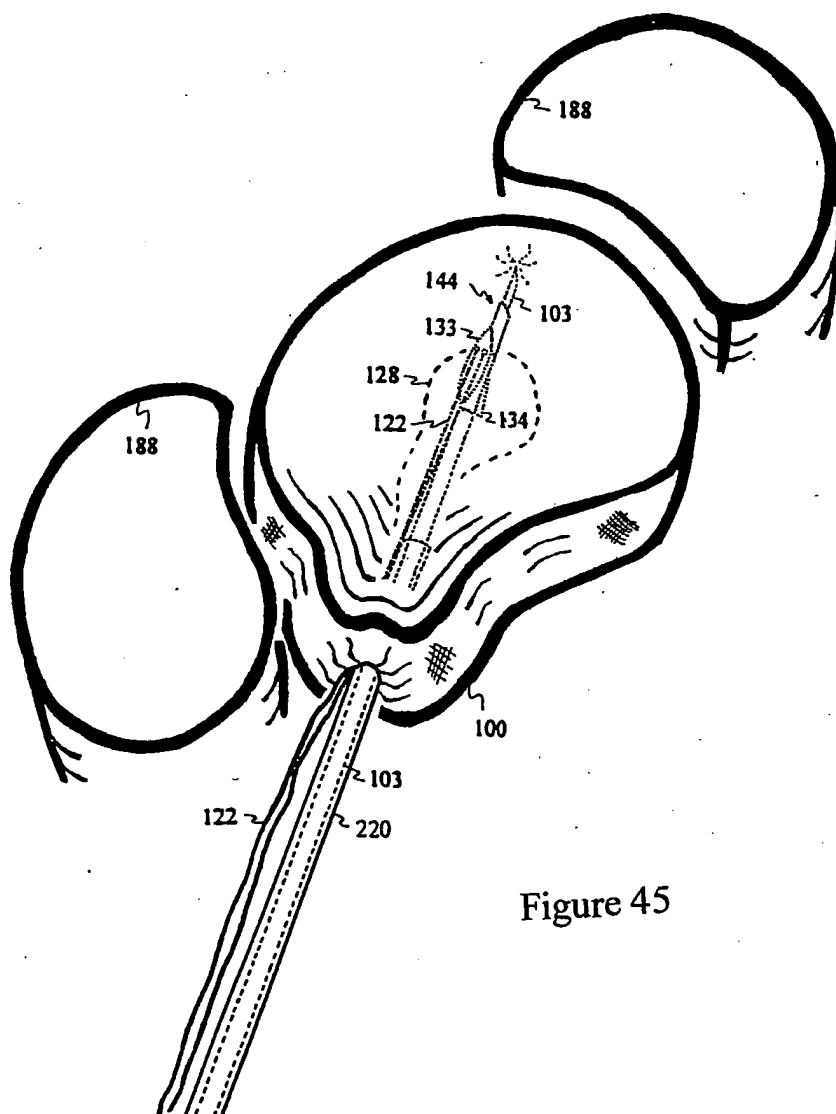
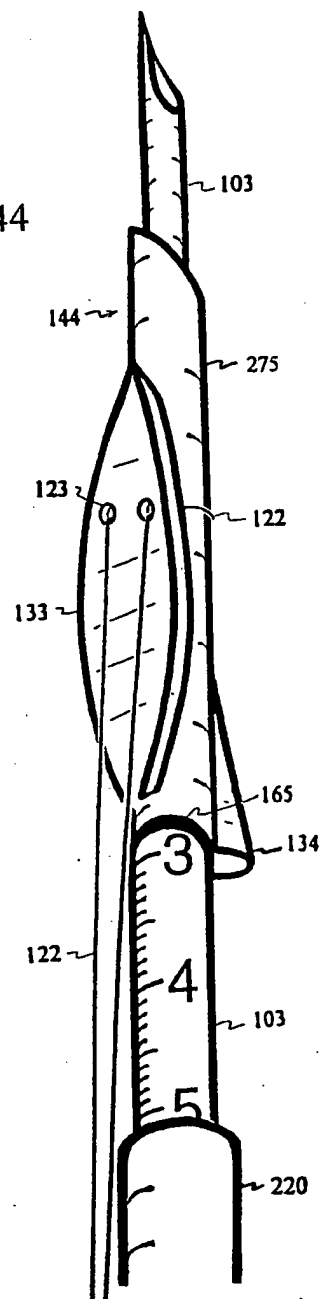


Figure 45

Figure 46

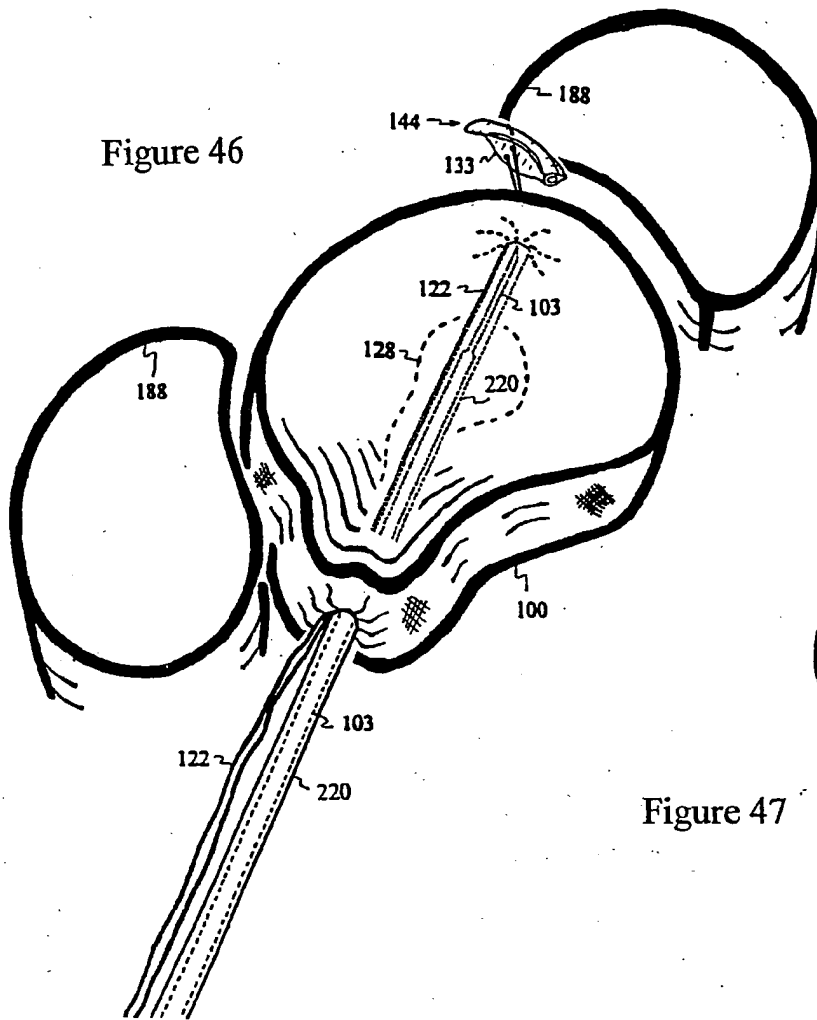


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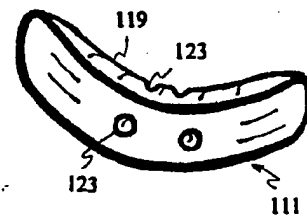
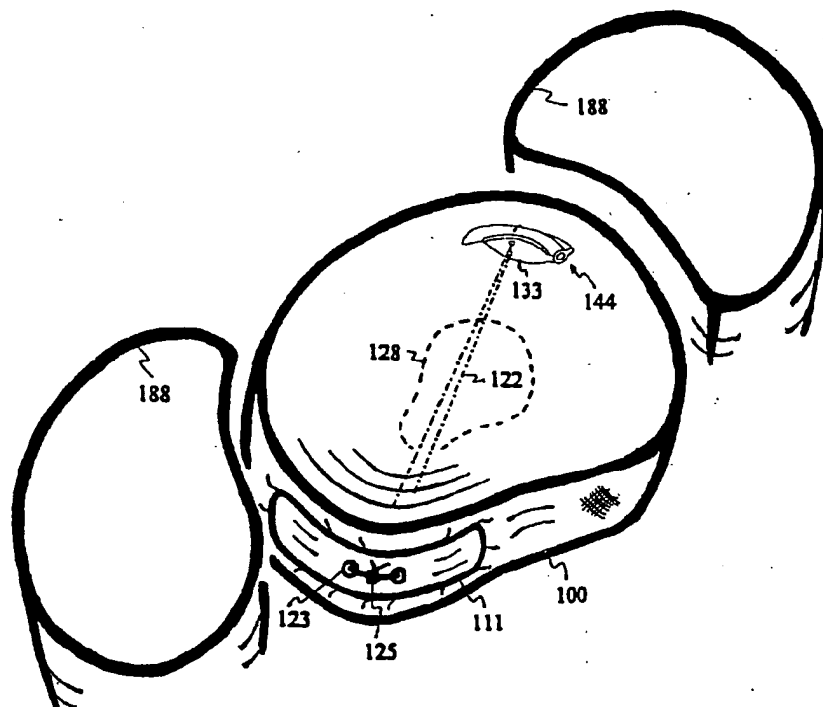


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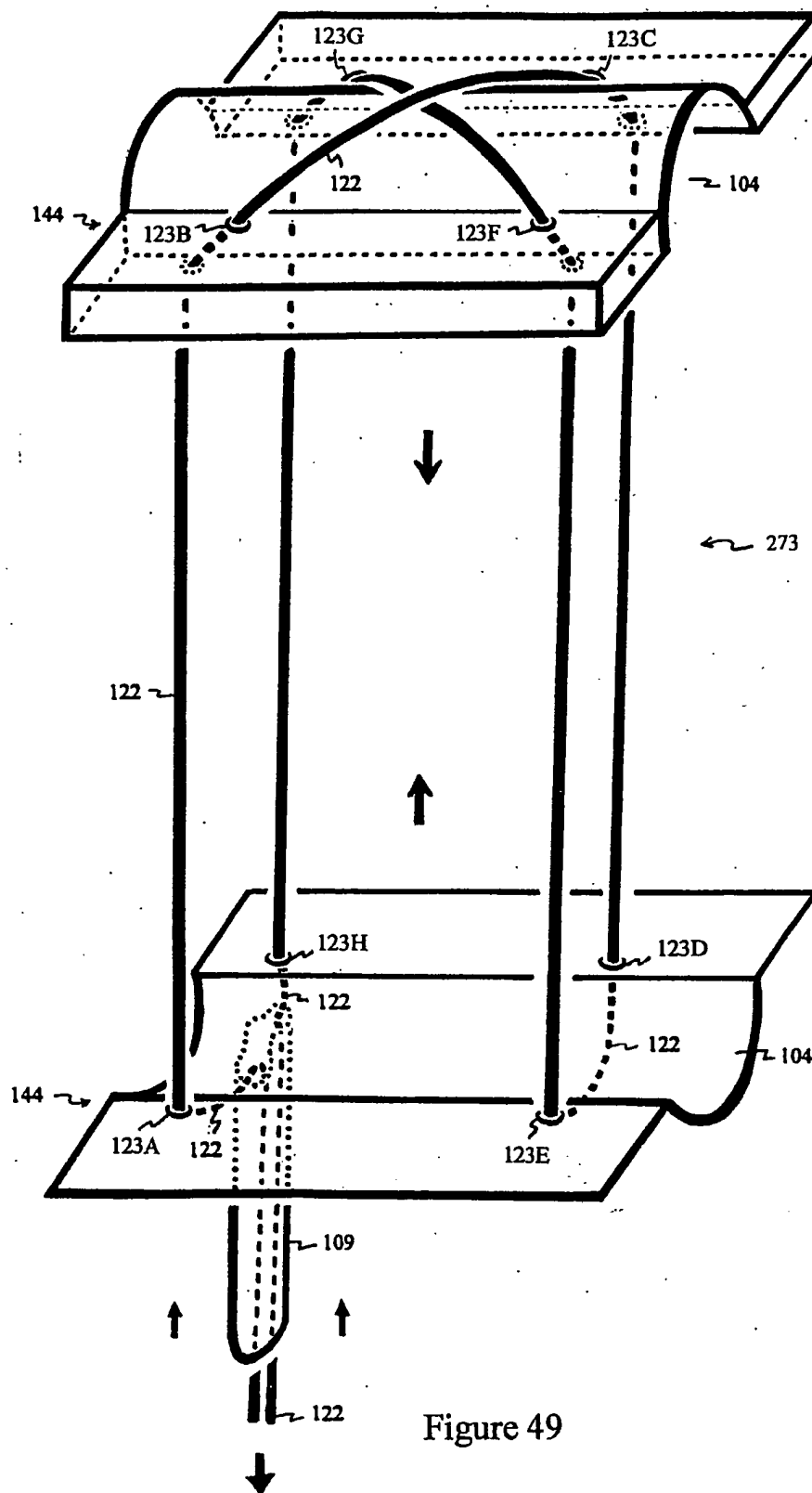


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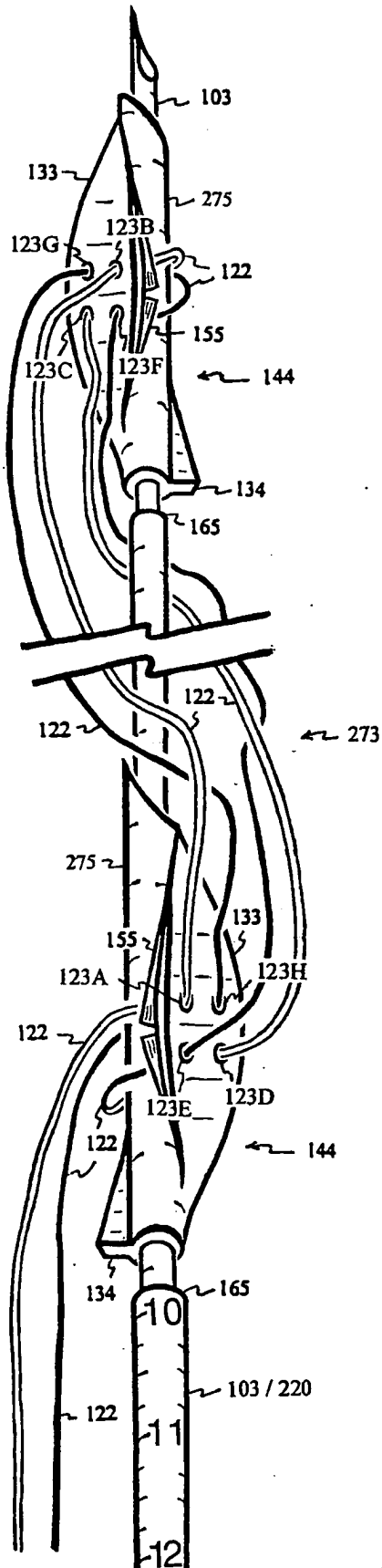


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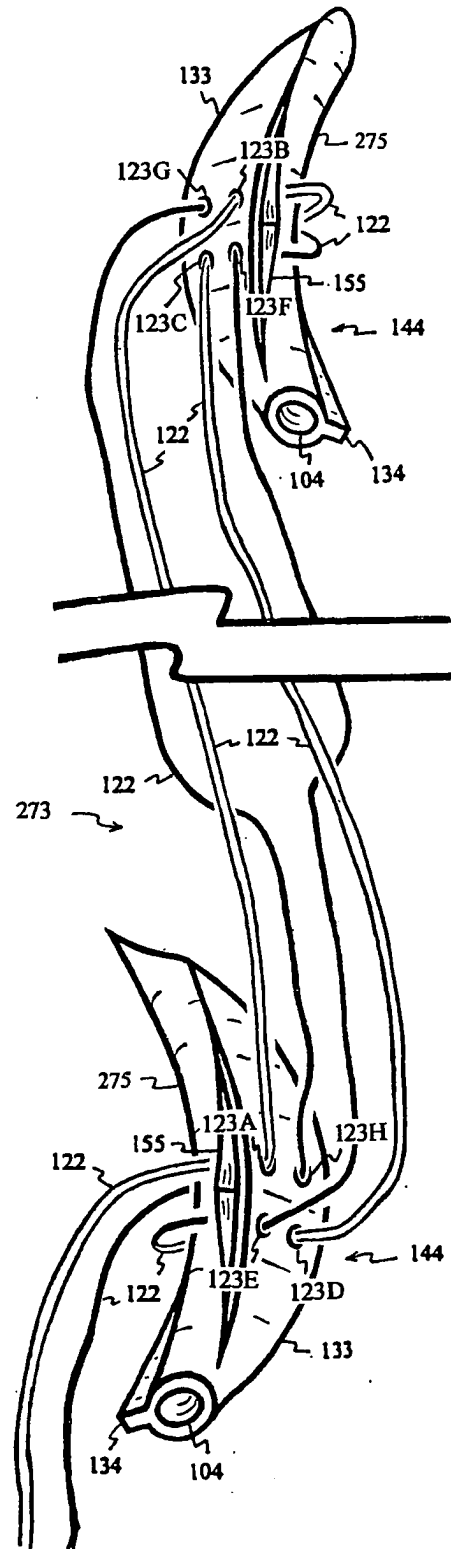


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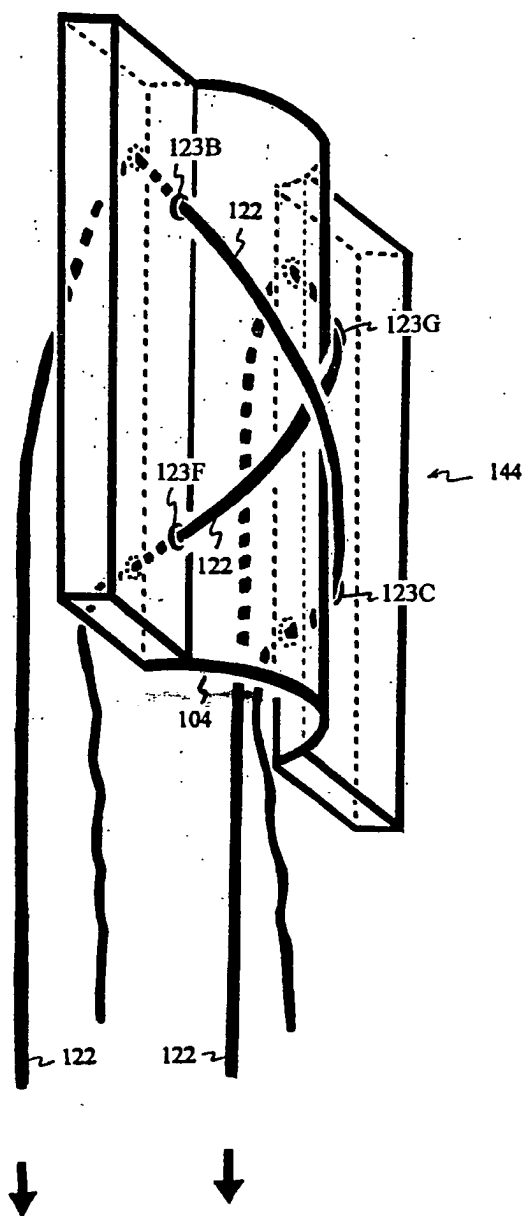


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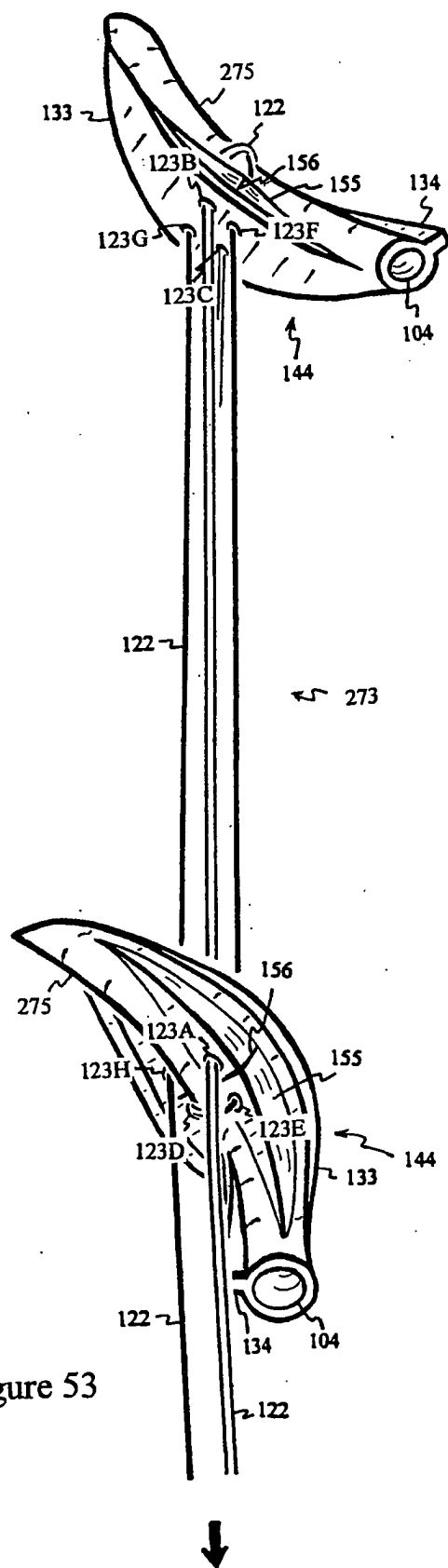


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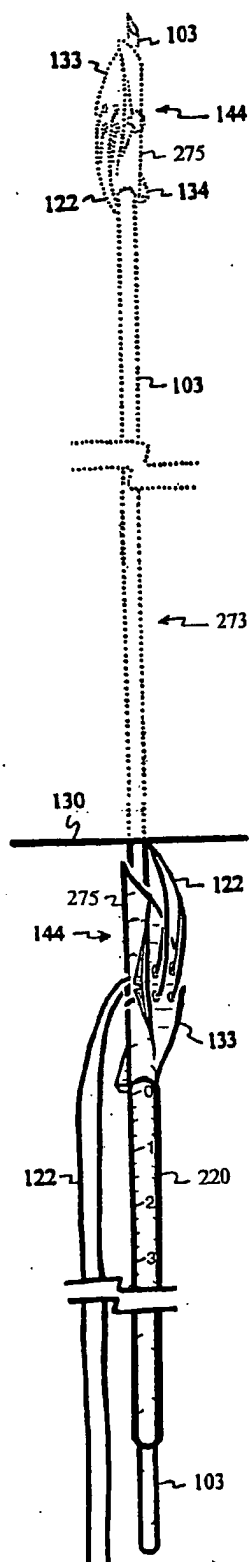


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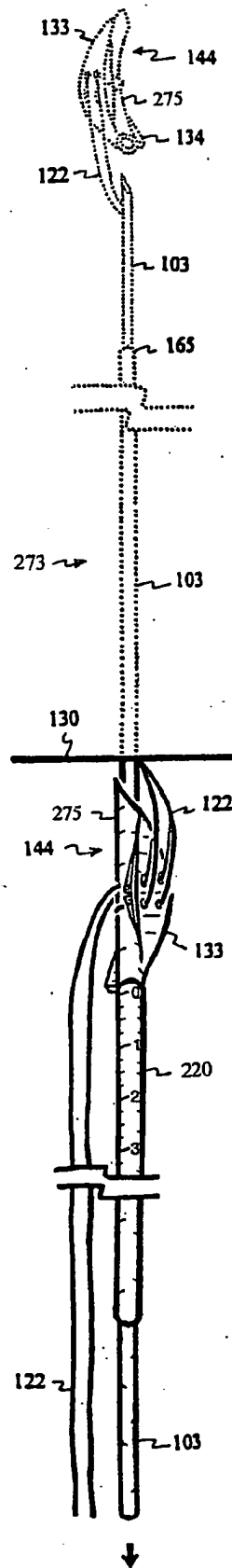


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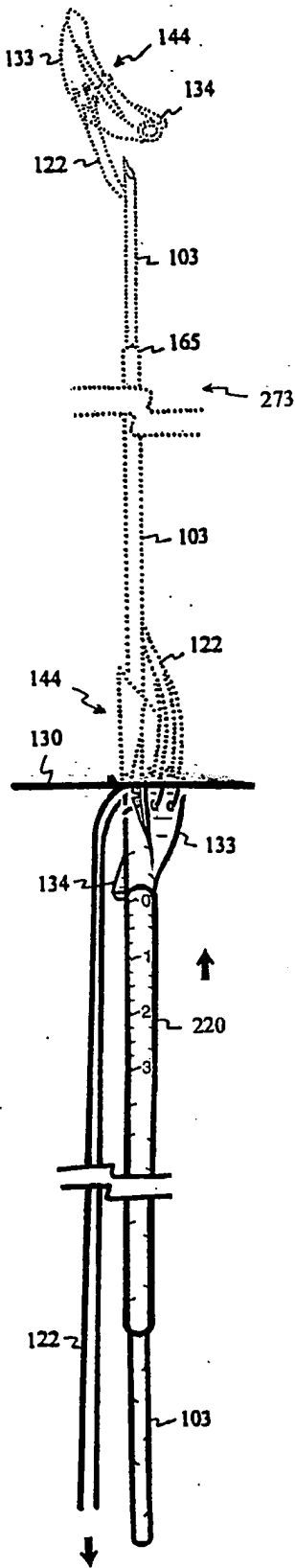


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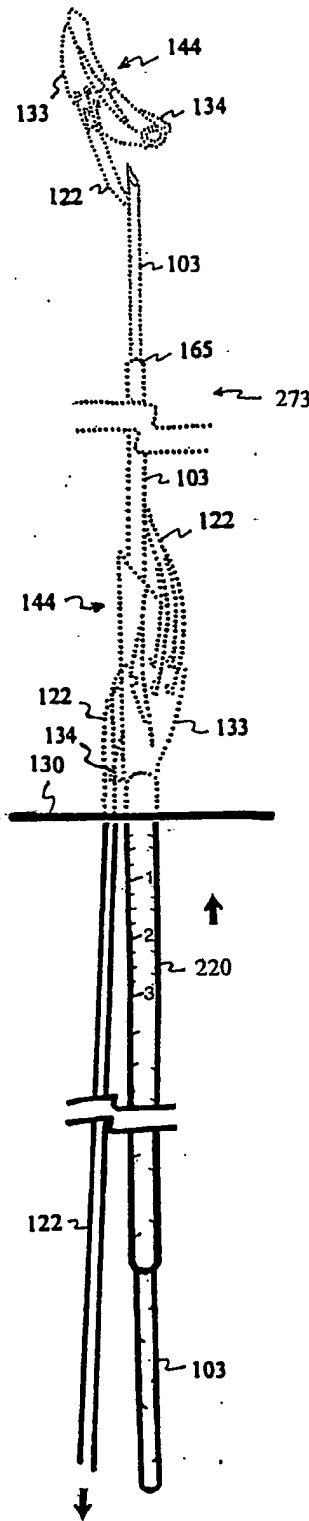


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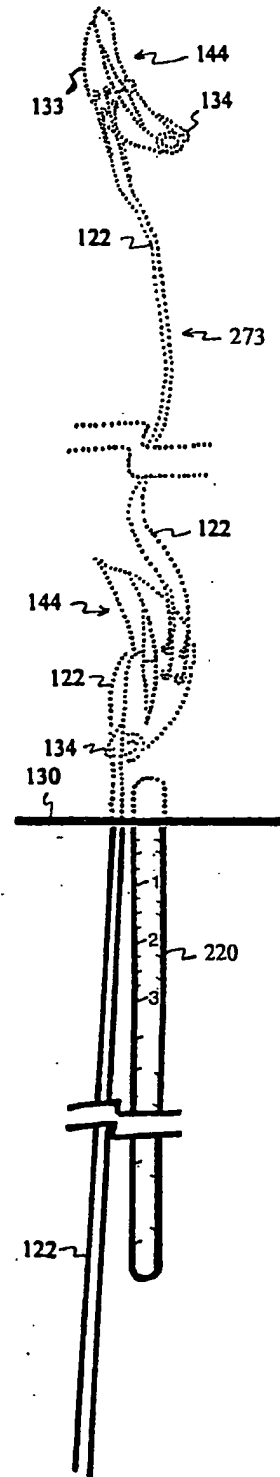


Figure 58

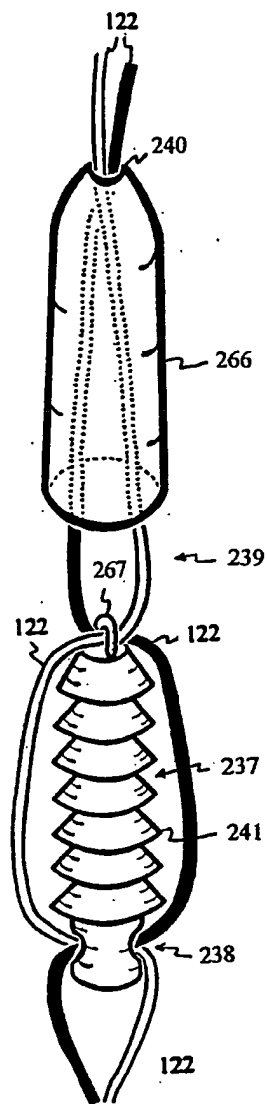


Figure 59

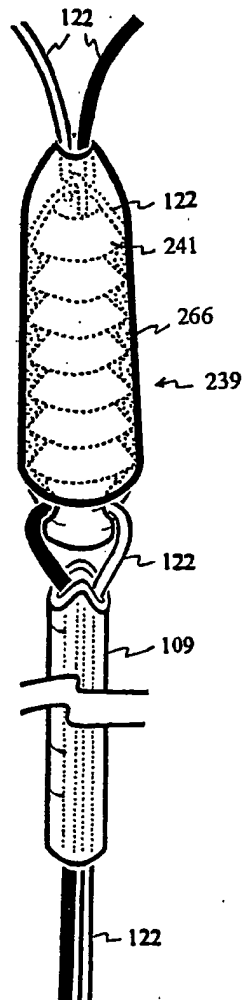


Figure 60

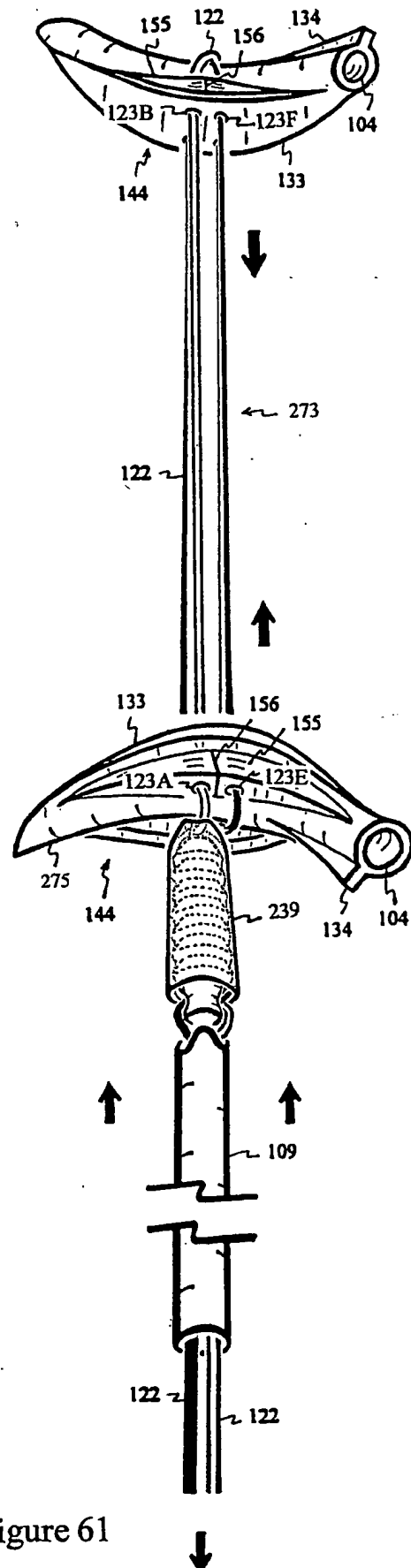


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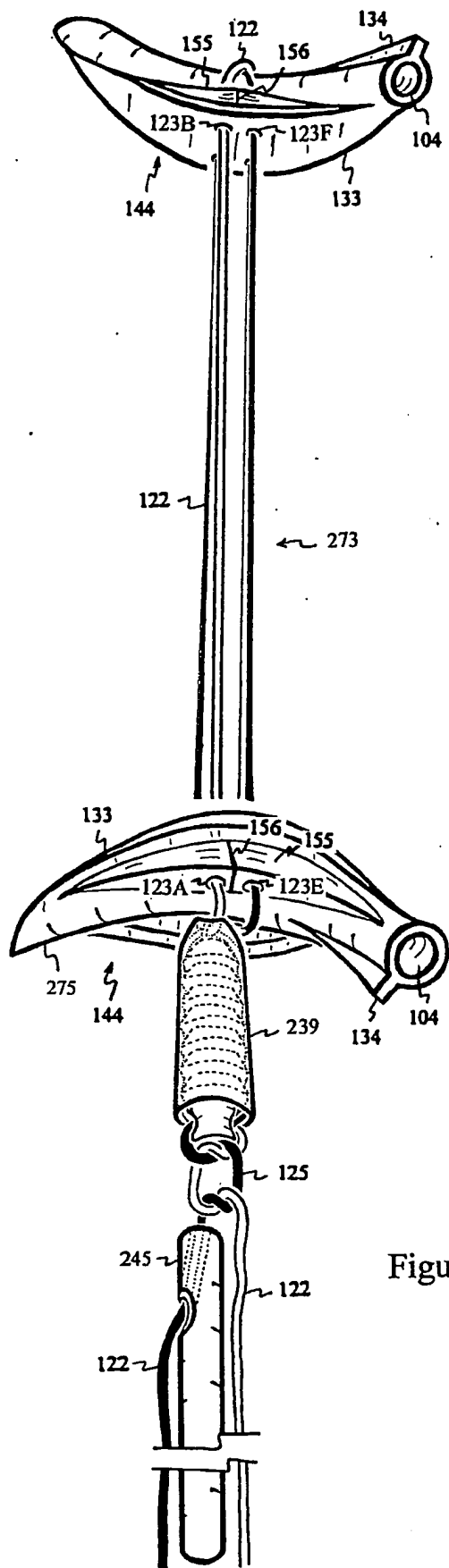


Figure 62

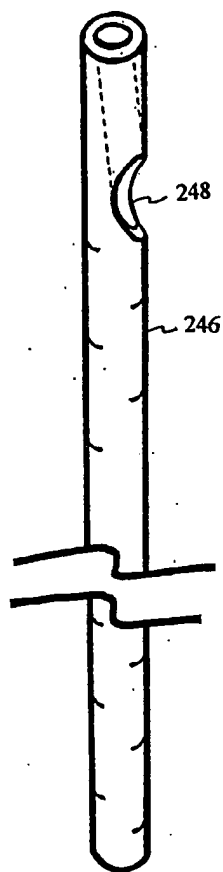


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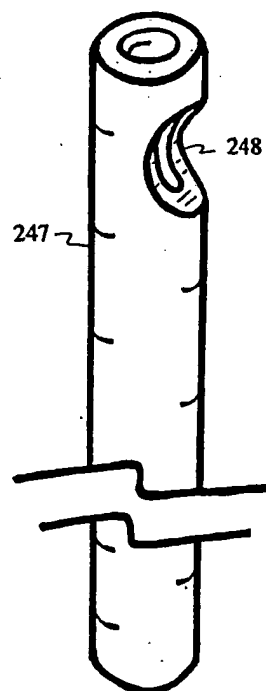


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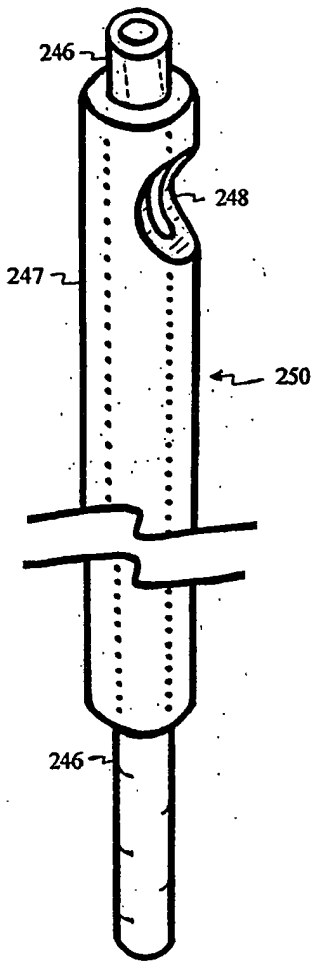


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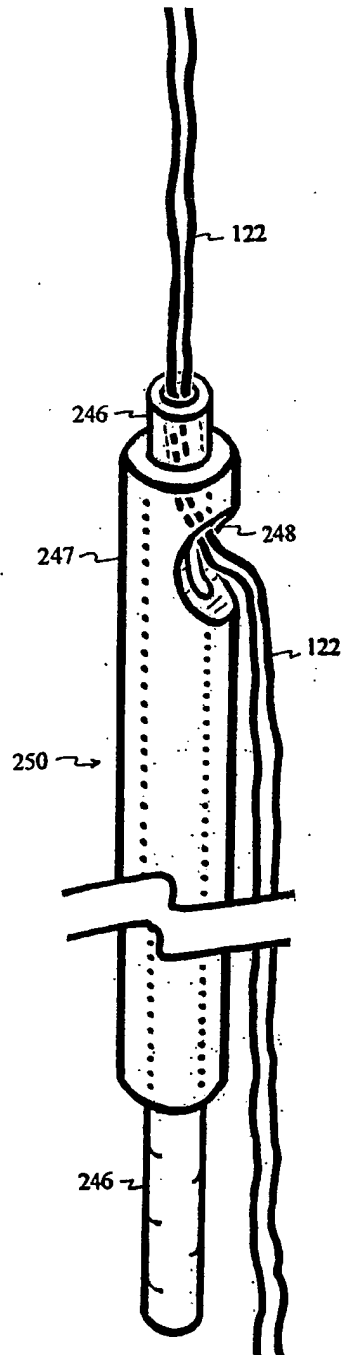


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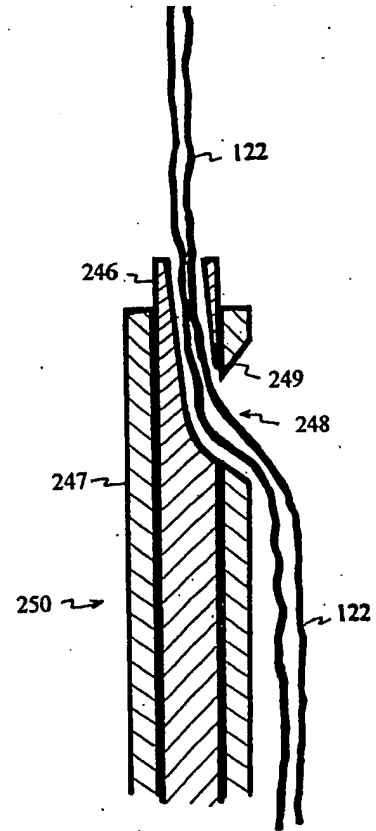


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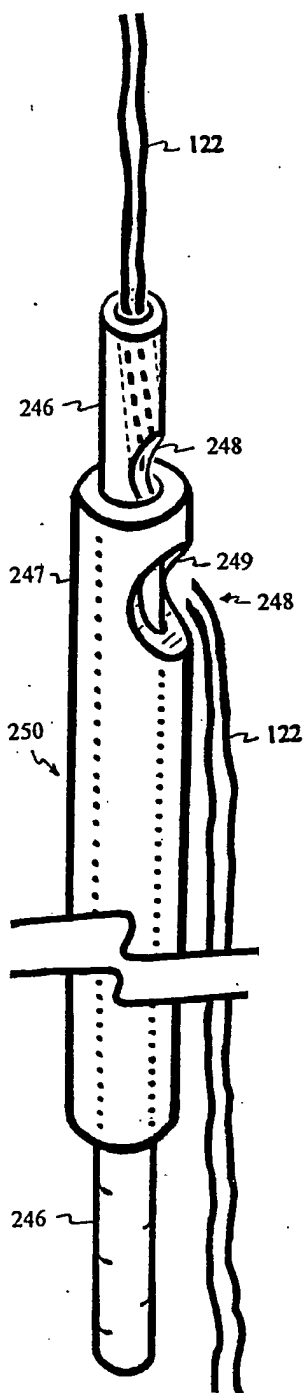


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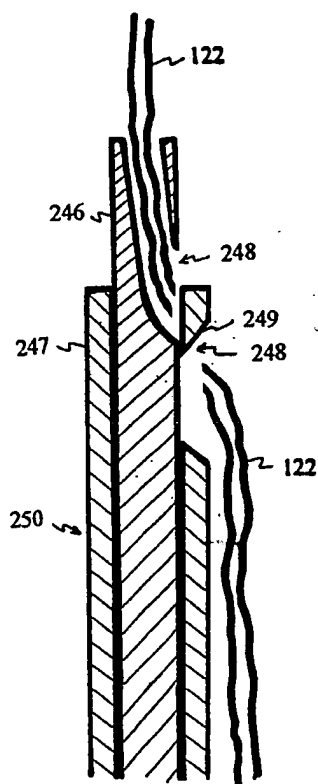


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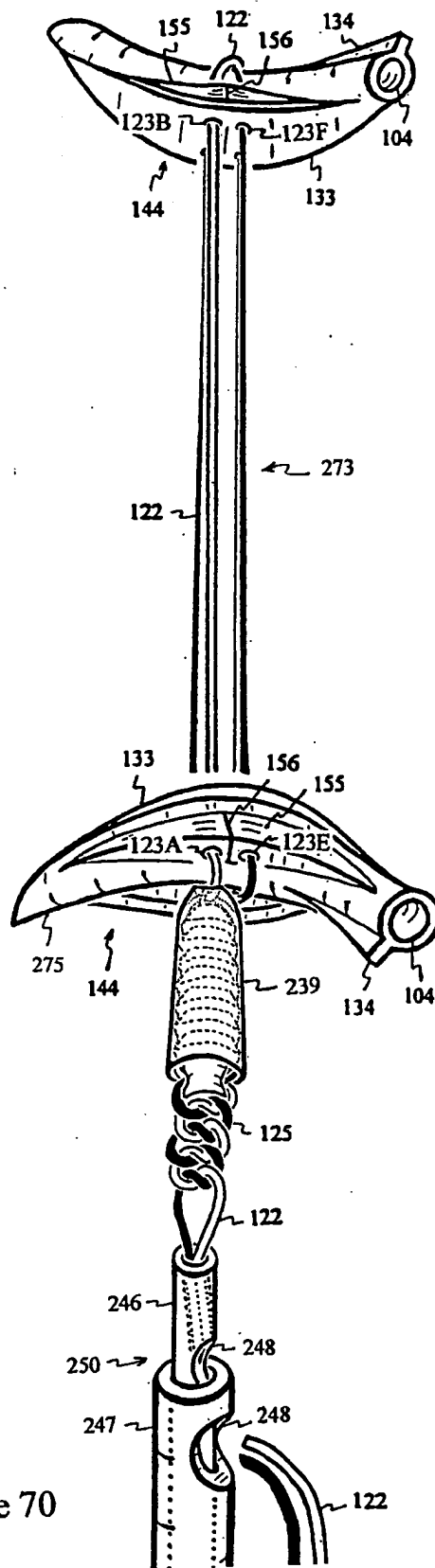


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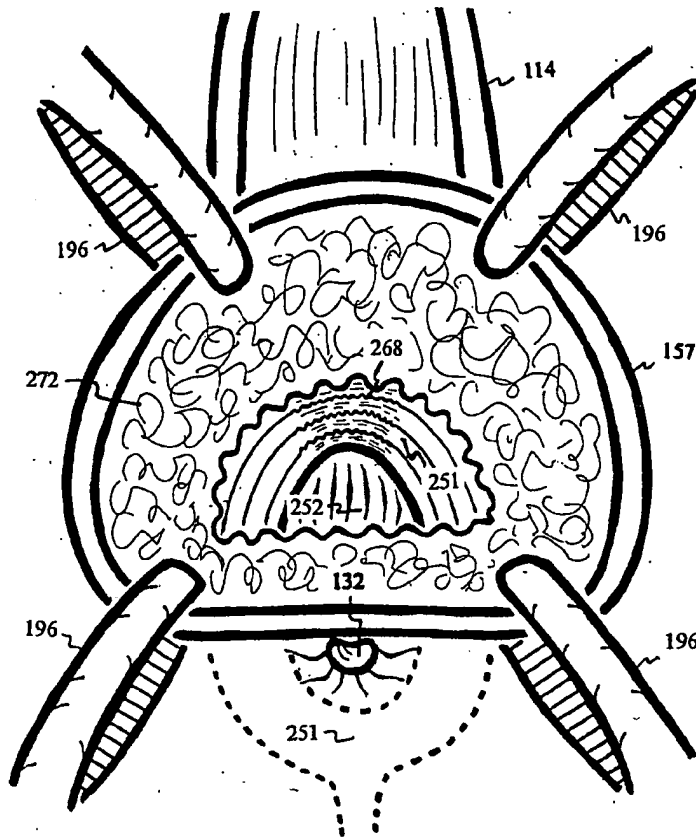
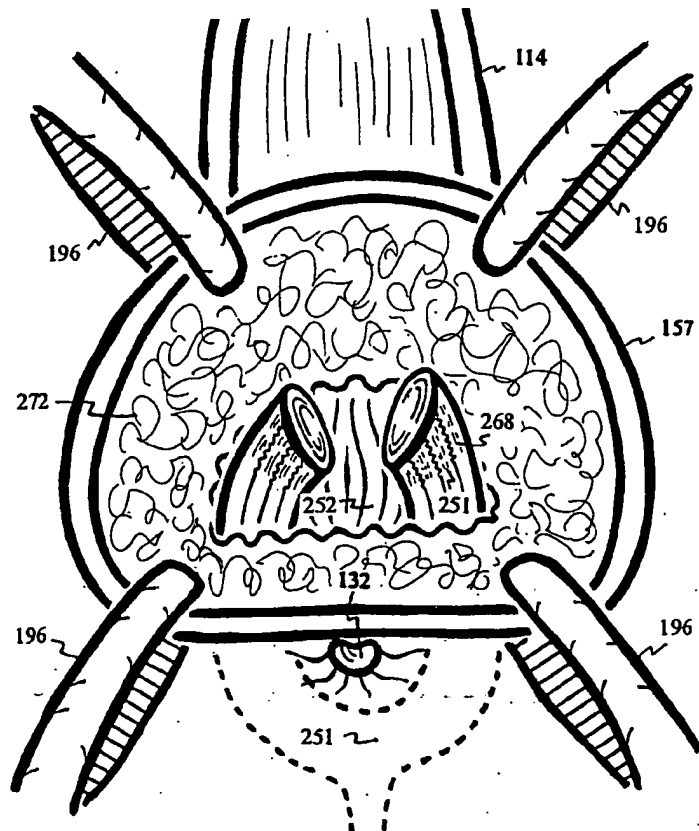


Figure 71

Figure 72
Prior Art



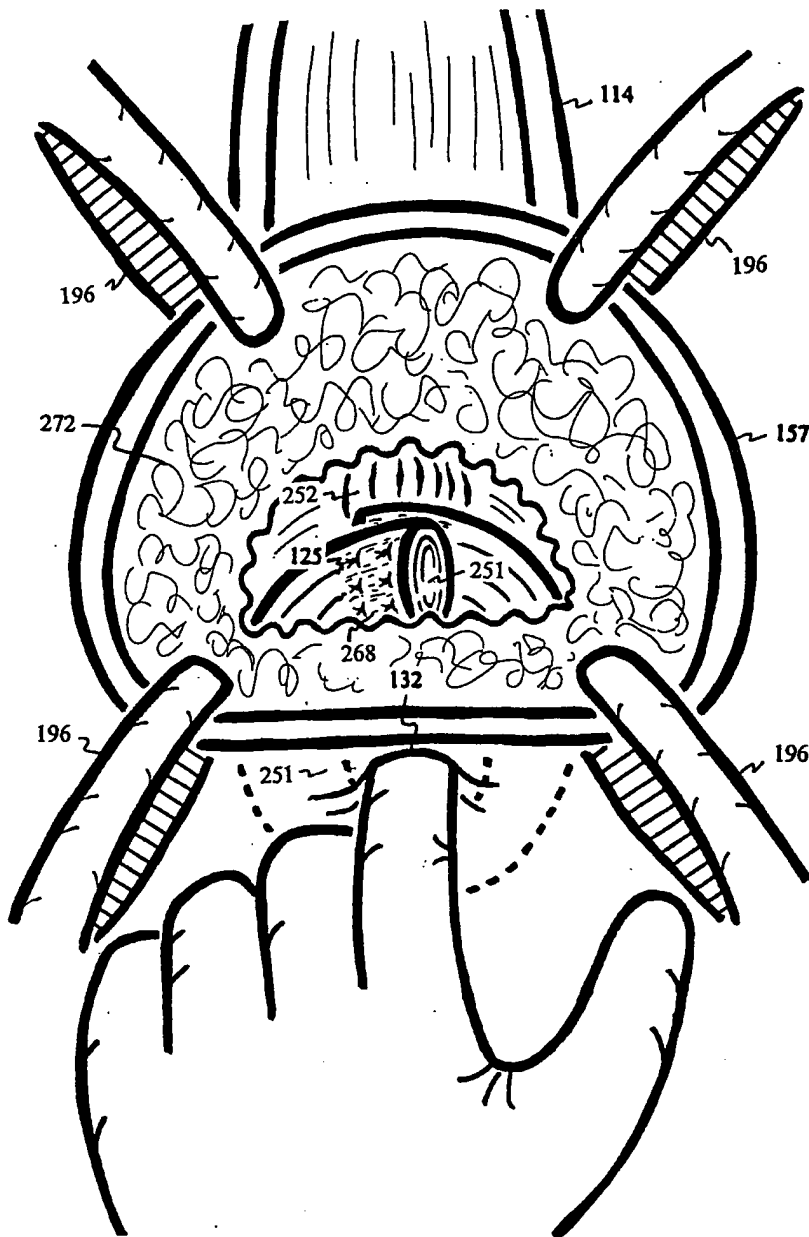


Figure 73
Prior Art

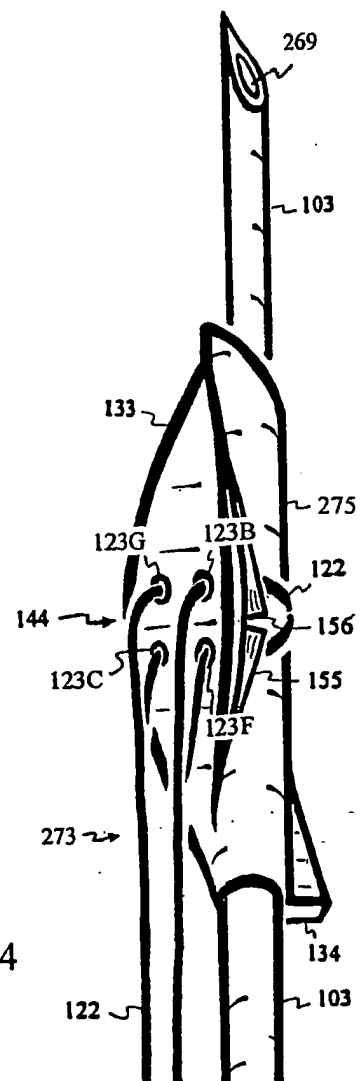


Figure 74

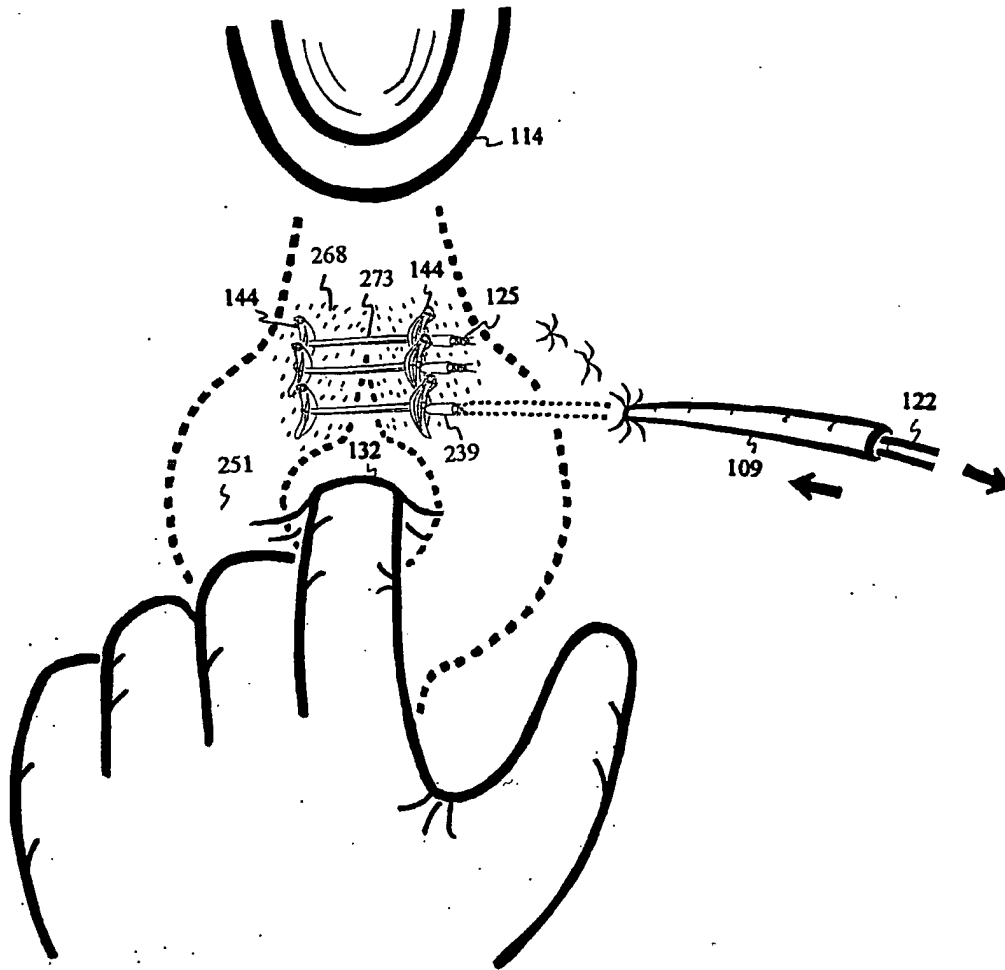


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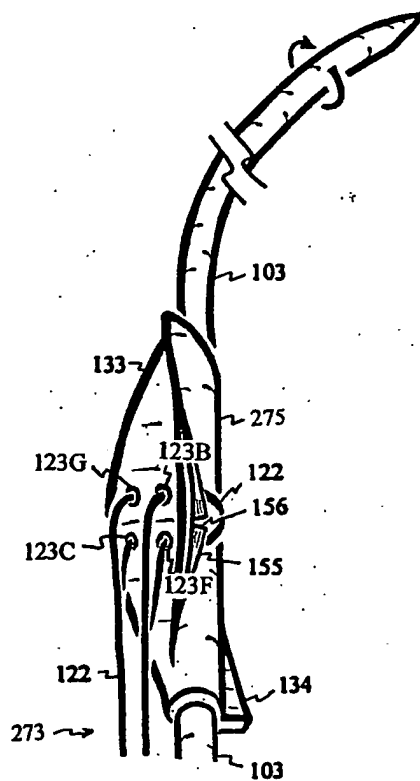


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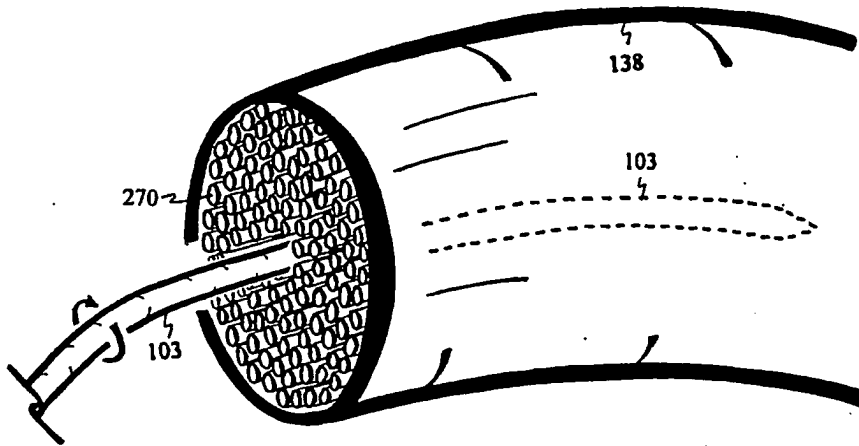


Figure 77

Figure 78

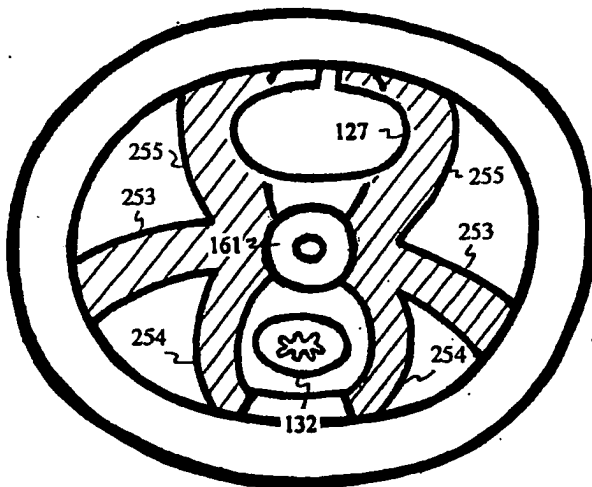
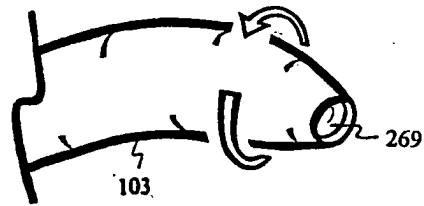


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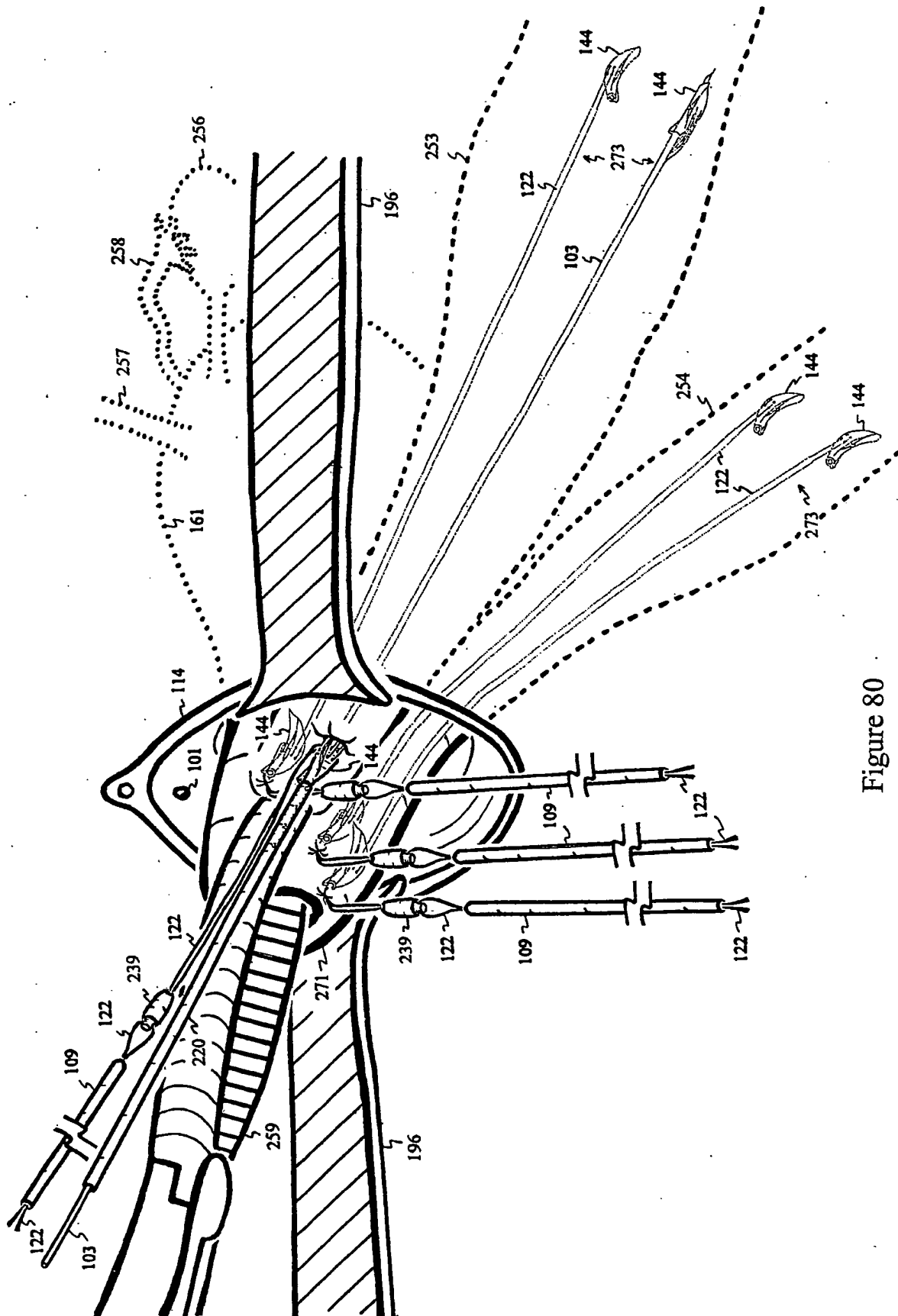


Figure 80

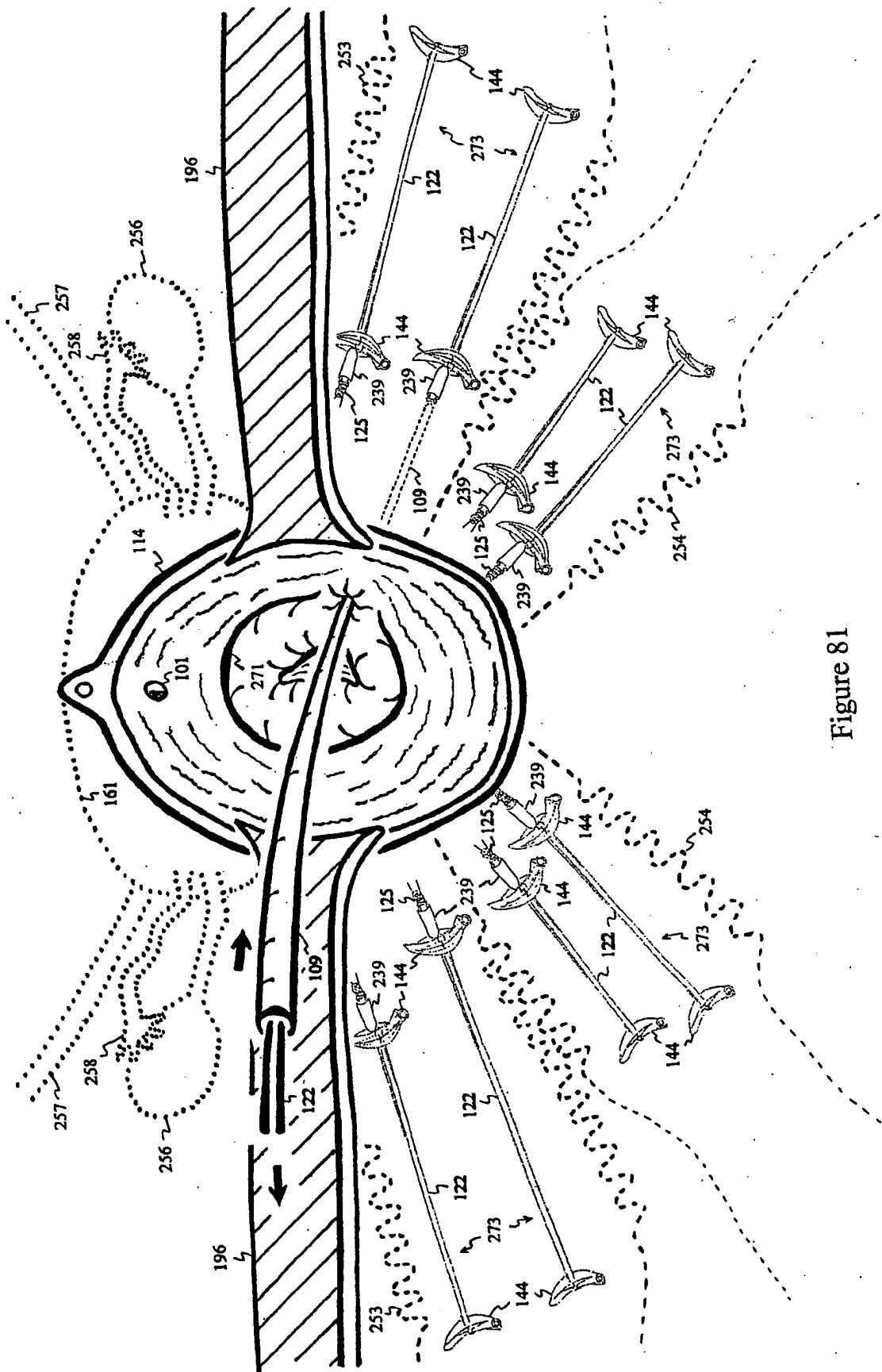


Figure 81

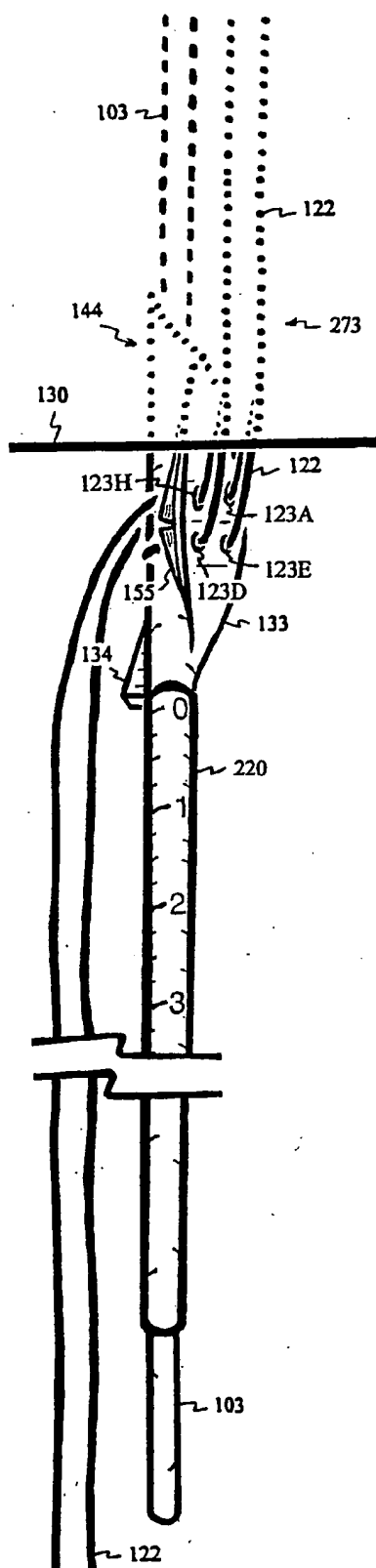


Figure 82

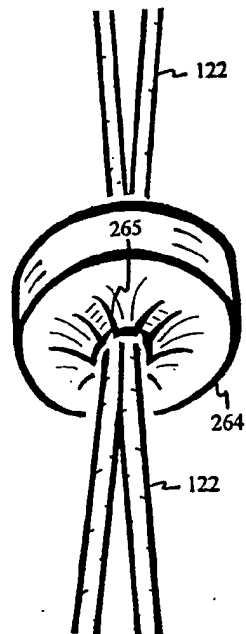


Figure 83
Prior Art

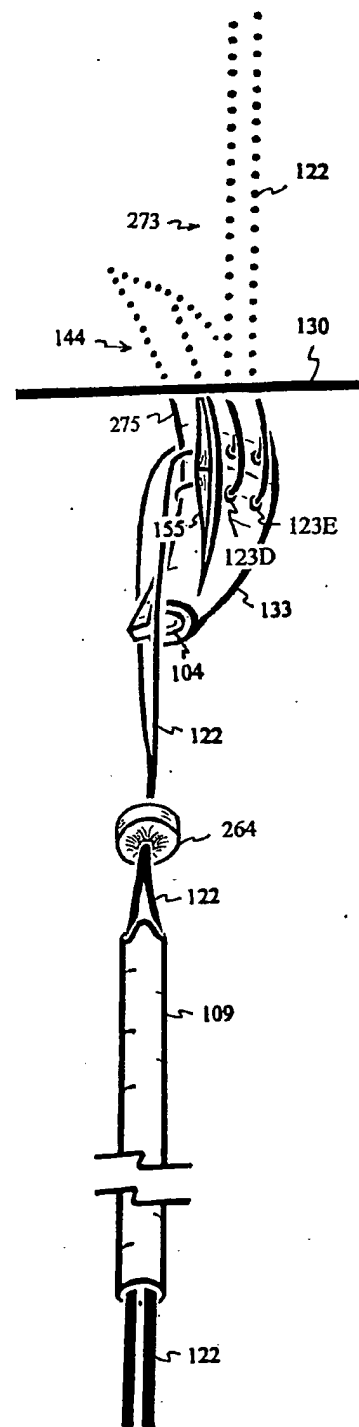


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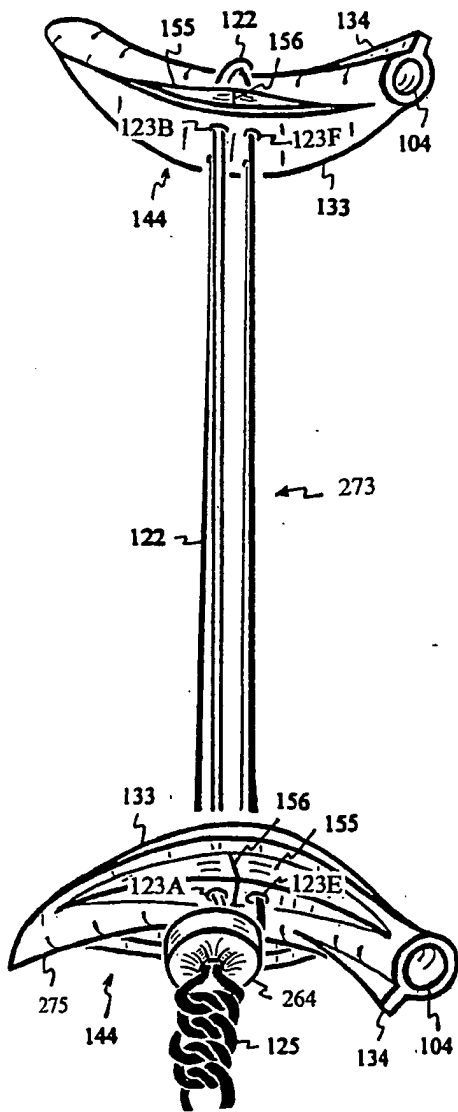


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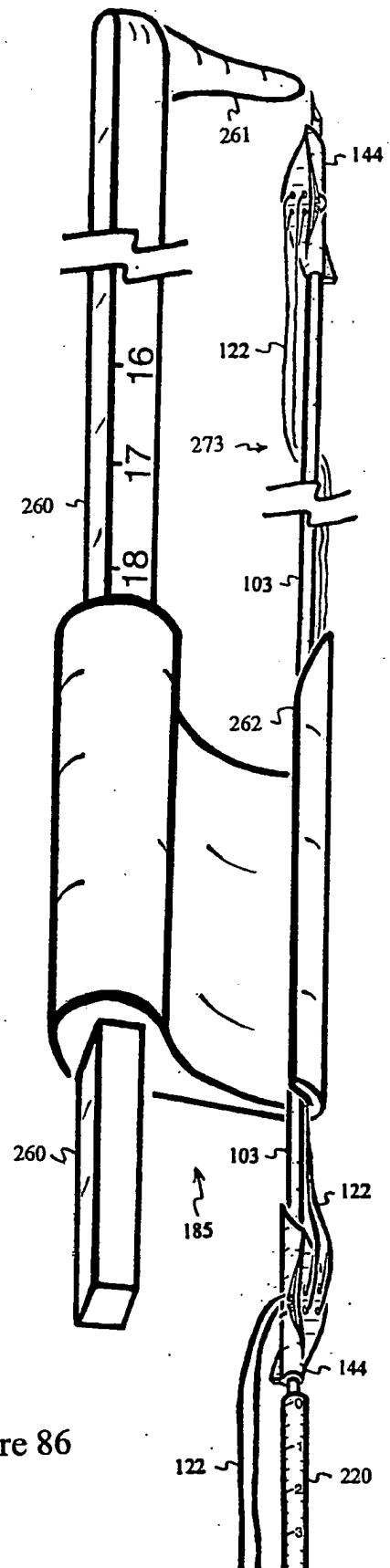


Figure 86

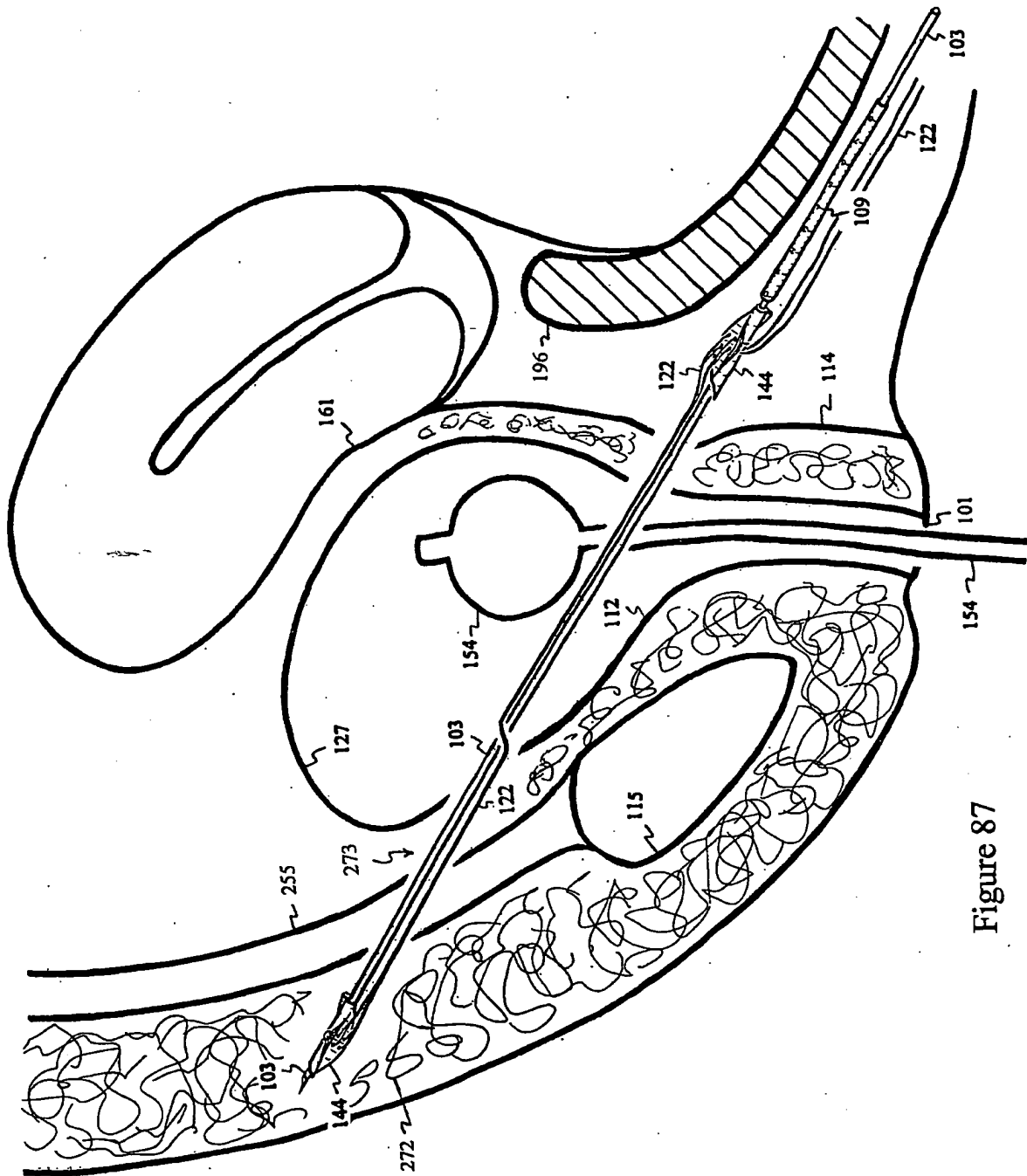


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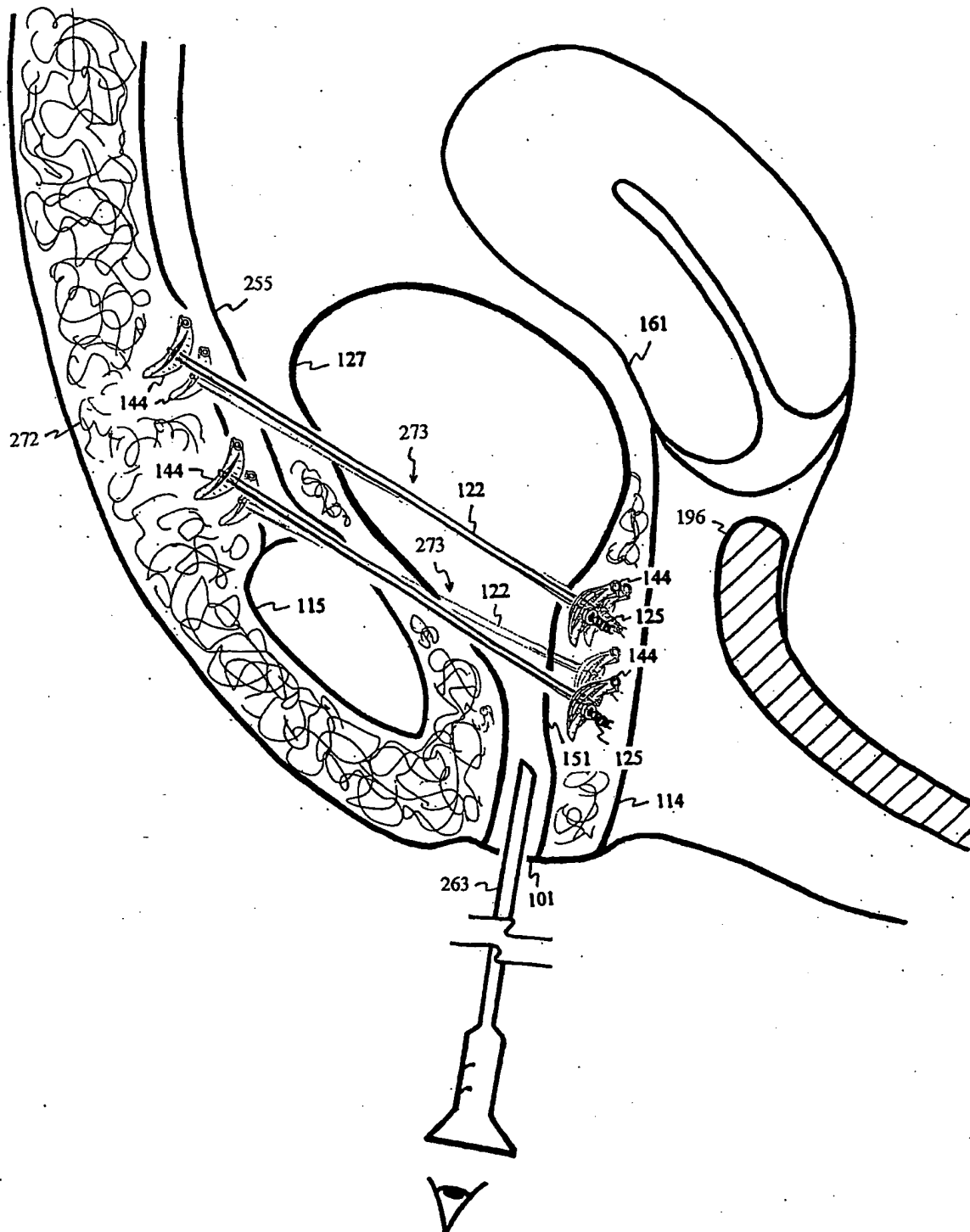


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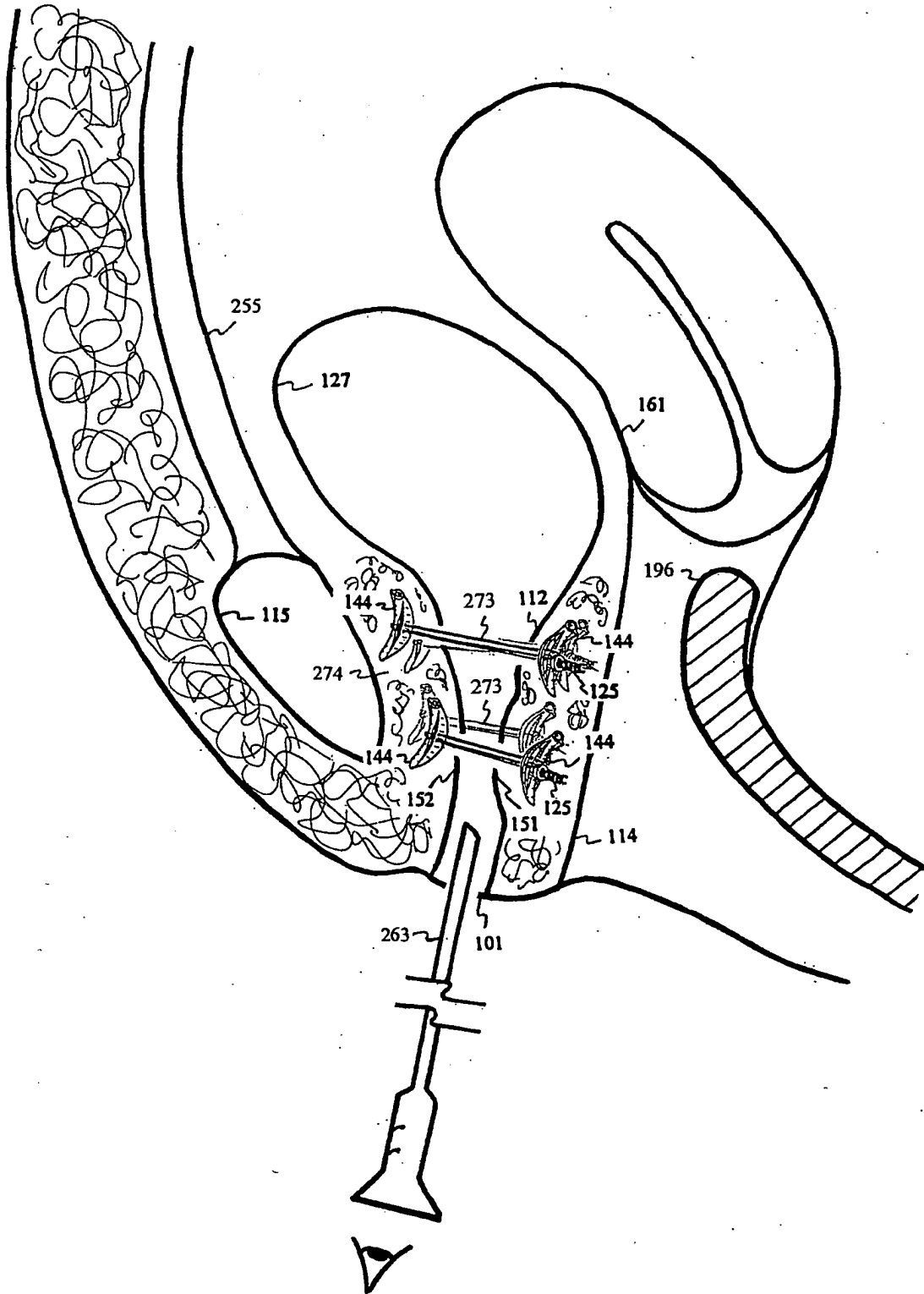


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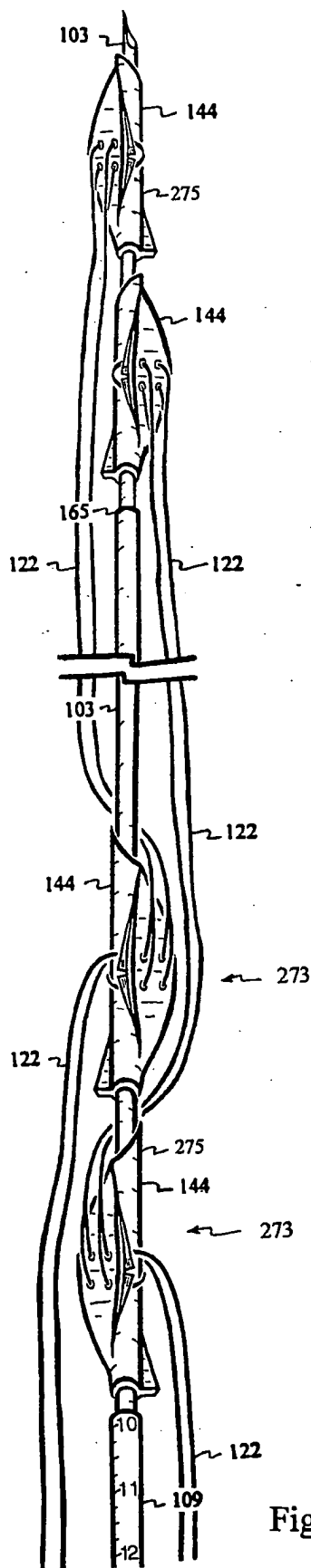


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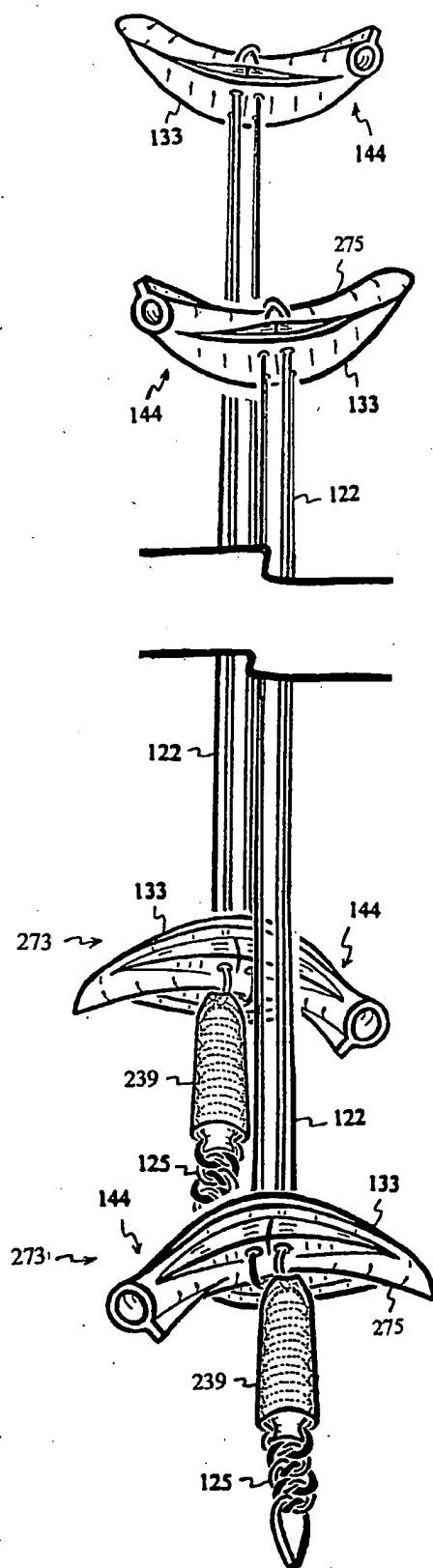


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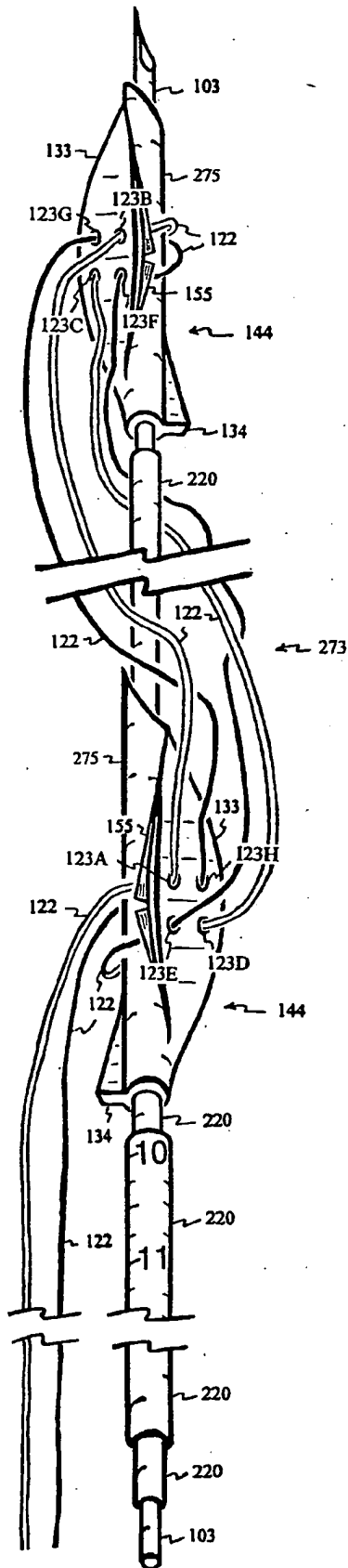


Figure 92

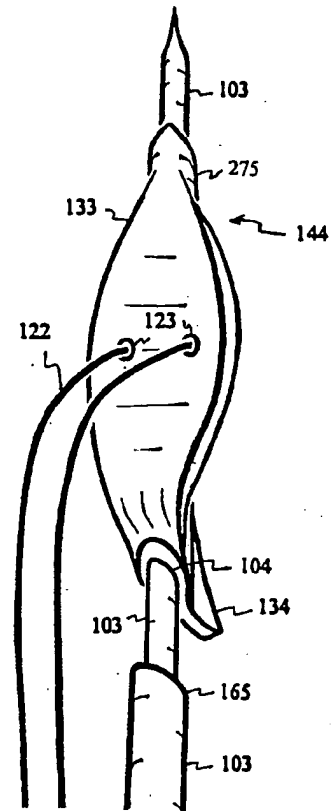


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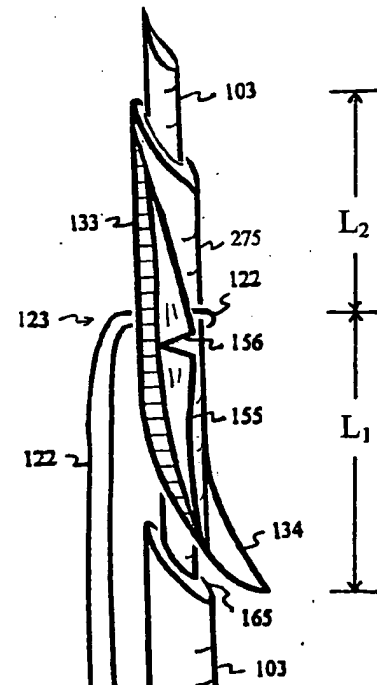


Figure 94

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/41399A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01 39671 A (SMITH & NEPHEW INC) 7 June 2001 (2001-06-07) page 2, line 1 -page 3, line 28 figures 1A,4 ---	1,21,32
A	US 6 117 161 A (FUJIKAWA RAY ET AL) 12 September 2000 (2000-09-12) column 5, line 48 -column 6, line 28 figures 8,9 ---	1,21,32
X	WO 00 40159 A (YEUNG JEFFREY E ;YEUNG TERESA T (US)) 13 July 2000 (2000-07-13) page 24, line 16 - line 30 figure 12 -----	80

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

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Date of the actual completion of the international search

22 April 2003

Date of mailing of the international search report

06/05/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
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Fax: (+31-70) 340-3016

Authorized officer

Compos, F

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/41399

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 51-79
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-50

Suture anchor/toggle of elastic material with a passage extending along its longitudinal axis, a suture opening and a guiding fin and/or platform to one side of the anchor body.

2. Claims: 80,81

Suture anchor insertion needle with a needle, a first sleeve around said needle and a second sleeve around said first sleeve.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/41399

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0139671	A	07-06-2001	AU 1804501 A	12-06-2001
			WO 0139671 A1	07-06-2001
			US 2002019649 A1	14-02-2002
US 6117161	A	12-09-2000	AU 6038796 A	24-12-1996
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			TW 387804 B	21-04-2000
			WO 9639083 A1	12-12-1996
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			CA 2358387 A1	13-07-2000
			EP 1139883 A1	10-10-2001
			WO 0040159 A1	13-07-2000
			US 6530933 B1	11-03-2003

(19) World Intellectual Property
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International Bureau



(43) International Publication Date
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PCT

(10) International Publication Number
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(51) International Patent Classification⁷: **A61F 2/06**

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(22) International Filing Date: 25 April 2005 (25.04.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/565,428 26 April 2004 (26.04.2004) US

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IN 46808 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): SCHWARTZ, Her-
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IN 46845 (US).

(74) Agent: NIEWYK, Anthony; Baker & Daniels, 111 East
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(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

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CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA,
MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM,
PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY,
TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU,
ZA, ZM, ZW.

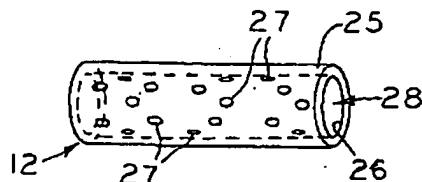
(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO,
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Published:

- with international search report
- before the expiration of the time limit for amending the
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amendments

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: STENT FOR AVASCULAR MENISCAL REPAIR AND REGENERATION



(57) Abstract: A surgical stent made of biocompatible material for im-
plantation in human tissue to enable blood and nutrients to flow from an
area of vascular tissue to an area of tissue with little or no vasculature.

STENT FOR AVASCULAR MENISCAL REPAIR AND REGENERATION

FIELD OF INVENTION

[0001] The present invention relates generally to surgical devices for repairing or regenerating body tissue and more specifically to surgical devices for repairing or regenerating soft tissues (i.e. articular cartilage, fibrocartilage, collagenous structures, ligaments, tendons, meniscus, spinal disc, TMJ disc etc...) of the joints (knee, hip, shoulder, temporomandibular joint, spine, fingers, ankle, toes, etc...), and to surgical methods using such devices.

BACKGROUND OF INVENTION

[0002] Meniscus tissue is comprised of a type of tissue known as fibrocartilage.

Fibrocartilage is present in the form of a disc (spine, temporo-mandibular joint), meniscus (knee), labrum (shoulder, hip), etc. In the knee, as shown in FIG. 1, the meniscus is a semi-lunar, wedge shaped tissue that sits on top of the tibia and articulates with the tibia and femur during gait activities. It acts as a shock absorber between the femur and tibia and distributes the compressive and shear loads from the curved condyles of the femur to the relatively flat plateau of the tibia. Similar to articular cartilage, much of the meniscus is avascular and aneural. However, as shown in FIG. 2, the meniscus has three zones of vascularity: red zone, red/white zone, and white zone. The red zone refers to approximately the outer peripheral third of the meniscus. This zone is rich in blood supply. The white zone can be found in the approximate inner peripheral third of the meniscus and is void of blood supply, and the red/white zone can be found in the approximate middle third and has a limited blood supply.

[0003] Injuries and pathologies occur in the meniscus, labrum, and disc that manifest themselves in the forms of tears, as shown in FIG. 3, defects, and degeneration. Various types and degrees of tears and defects in the knee meniscus can and do occur often as a result of some twisting action in the knee or as a result of repetitive impact over time. Similar actions in the other joints can result in similar defects and tears in the similar structures present in those joints. Meniscus degeneration can also occur as a result of aging so that soft or hard areas develop in the tissue such that even common activities such as squatting can cause meniscal tears and defects.

[0004] Common surgical procedures for treating meniscal damage include repairing the tears and complete or partial meniscectomies. Repairing a tear is commonly performed when the tear is a longitudinal vertical tear in the vascular (or red) zone of the meniscus. The tear walls can be rasped or trephined to induce bleeding, especially when the tear is just beyond the borders of the red zone (i.e. in the red/white zone). The tear is stabilized with suture or some other repair device such that the relative motion of the tear faces is minimized or eliminated during load bearing. Also, the knee capsule tissue (i.e. synovium) is sometimes rasped to induce bleeding of this highly vascularized tissue into the joint with the intent to provide a better healing environment for meniscal tears. Many devices and surgical procedures exist for repairing meniscal tears by approximating the faces of the meniscal tear. Examples of such devices and procedures are disclosed in the following U.S. Patents 6,319,271; 6,306,159; 6,306,156; 6,293,961; 6,156,044; 6,152,935; 6,056,778; 5,993,475; 5,980,524; 5,702,462; 5,569,252; 5,374,268; 5,320,633; and 4,873,976. The other common meniscal procedure, meniscectomy, involves the surgical removal of part of or all of the meniscus. Such procedures have commonly been performed in the case of "unrepairable" or complex tears such as radial tears, horizontal tears, vertical longitudinal tears outside the vascular zone, defibrillation, and/or degeneration because defects that occur in the avascular (white) or limited vascular (red/white) areas typically do not heal. Meniscectomies typically provide immediate pain relief and restoration of knee function to the patient; however, with the absence of the meniscus, the long term effect on the knee can be cartilage wear on the condylar or tibial plateau surfaces and the eventual development of an arthritic condition such as osteoarthritis. Osteoarthritis is a result of cartilage degradation that is associated with chronic knee pain and often leads to total joint reconstruction. It is for these reasons that meniscal scaffolds and implants have been developed to regenerate or replace the tissue that is removed during a partial or total meniscectomy (see, for instance, U.S. Patents 6,042,610; 5,735,903; 5,681,353; 5,108,438; 5,007,934; and 4,880,429).

[0005] Clinical experience indicates that white zone and red/white zone tears and defects typically do not heal even if they are stabilized with standard repair techniques. The option of not treating these types of defects is known to result in propagation of tears and defects and degeneration of the meniscus and subsequent degeneration of the articular cartilage and

development of osteoarthritis. However, studies performed by Dr. Steven Arnoczky in animals [Arnoczky SP, Warren RF, Spivak JM; J Bone Joint Surg Am. 1988 Sep;70(8):1209-17, "Meniscal repair using an exogenous fibrin clot. An experimental study in dogs."] and human clinical experience has shown that if the white or red/white zone defect surfaces are in contact with a blood clot (i.e. fibrin clot) then such tears or defects have a greater propensity to heal. So, if a surgeon were to deliver and fix a blood or fibrin clot to tear or defect surfaces, then healing would likely occur. Most surgeons, however, do not attempt to deliver and fix blood/fibrin clots to facilitate the repair of these types of tears because of the technical challenges. These meniscal procedures are typically performed using arthroscopic techniques (i.e. through small portals using an arthroscope or camera to visualize the surgical site). In order to see clearly through the arthroscope, the surgeon is required to constantly infuse the knee with fluid (i.e. saline solution, Ringer's solution, etc.); however, if he or she is trying to deliver a blood clot and fix it in the white or red/white zone defect, then the fluid would typically be turned off so that the clot does not disintegrate during the delivery and fixation stage. With the fluid turned off, the surgeon has the technical challenge of not being able to see the surgical site clearly; therefore, a technical dilemma exists: in order to see more clearly the fluid needs to be turned on, but in order to deliver and fix the clot the fluid needs to be turned off. Therefore, the technical challenges are too difficult to overcome in an arthroscopic environment; the surgeon therefore typically excises injured or degenerated white zone and red/white zone tissue (i.e. performs a partial or total meniscectomy). Performing these procedures in a non-arthroscopic setting (i.e. open condition) is not a viable option due to patient expectations, increased morbidity, and increased risks associated with larger incisions.

[0006] Currently, tissue engineering scaffolds are being developed to replace the meniscal tissue that has been removed, such as for instance, (ReGen Biologics' Collagen Meniscal Implant or CMI and DePuy's (a Johnson & Johnson company) small intestine submucosa meniscal implant. These implants are being developed to regenerate meniscal tissue; however, they are effective only when the implant is placed in direct contact with the vascular (red) zone of the meniscus. Therefore, if the defect area is confined to the avascular zone only, then one of the meniscal implants referred to above will not regenerate that tissue. For the defects that are

confined to the avascular zone only, the surgeon must then remove only that portion of the meniscus that is injured and/or diseased and would not expand the defect into the vascular zone, thus removing "good tissue." So, for those patients with avascular zone defects, the only option today (and even in the future with the above mentioned tissue engineered scaffolds in their current configuration) is a partial meniscectomy with no tissue engineering replacement solution. Unfortunately for the patient who receives the partial meniscectomy, the long term prognosis includes chronic knee pain, break down of the articular cartilage, osteoarthritis, and even eventual total knee replacement.

[0007] Similar to the knee meniscus, other structures are found throughout the body that have avascular and vascular anatomies in close proximity where the avascular portion of these structures have very little propensity for healing. Some of these other structures are the labrum of the hip joint, the labrum of the shoulder joint, the meniscal-like structure of the wrist, the discs of the spine, the disc of the temporomandibular joint, diseased cardiac muscle (i.e. due to reduced blood flow from cardiovascular blockage) to name a few.

[0008] Also, in a spinal application, when a patient presents to a surgeon with a bulging or herniated or ruptured spinal disc, the adjacent vertebral bone is often sclerotic (i.e. thickened or denser). Since much of the nutrients for the spinal disc are delivered via diffusion through the vertebral endplates, the sclerotic bone could tend to decrease the amount of nutrients delivered to the disc, thus contributing to the diseased state of the disc.

SUMMARY OF THE INVENTION

[0009] The present invention is directed toward devices and surgical methods for repair and regeneration of diseased or damaged fibrocartilage and soft tissues such as the meniscus in the human knee joint. The devices and methods can also be applied toward the repair and regeneration of diseased or injured other fibrocartilage and soft tissues of the knee, hip, shoulder, temporo-mandibular joint (TMJ), spine, fingers, wrist, ankle, etc.

[0010] The invention comprises, in one form thereof, a channel for blood, blood components, and cells to travel from a vascular area of tissue to an avascular or partially vascular area to

facilitate healing and/or regeneration in these areas that would otherwise have a lower healing and regeneration capacity.

[0011] It is an objective of the present invention to provide a channel for blood, blood components and/or nutrients, and cells to travel from the vascular (red) zone such as in knee meniscus or synovium (i.e. knee capsule) to the avascular (white) or partially vascular (red/white) zone to facilitate healing and/or regeneration in these zones.

[0012] It is also an objective of the present invention to provide a biocompatible tube. The tube can have a stopping brim to prevent it from being inserted completely through the tissue. The tube is intended to be located within meniscal tissue such that it provides a channel from the vascular zone of the tissue (meniscus or synovium) to the avascular (white) or partially vascular (red/white) region. The tube wall can have openings, perforations, holes, or porosity that allow for blood, nutrients, and cells to enter the tube through the walls of the tube or stent. The tube wall exterior can be roughened or have protrusions or threads that will facilitate its fixation to the meniscal tissue. The "tube" could be a cylinder with a porous configuration such that blood, nutrients, and cells could travel within and through the device.

[0013] It is also an objective of the present invention to provide a pathway through which blood, nutrients, and cells can pass to facilitate healing of an avascular (or partially vascular) tear/defect or to facilitate regeneration of avascular (or partially vascular) tissue when an implant is placed in addition to the tube(s) after performing a partial meniscectomy. In the case of a partial meniscectomy, the channel could function to deliver a blood or fibrin clot to the volume space of meniscus that was removed such that the clot acts as a scaffold in which cells can travel and propagate, thus, facilitating regeneration of that portion of the meniscus. In this case the open channel would also provide the access of the vascular area components to the *in situ* scaffold (i.e. blood or fibrin clot).

[0014] It is also an objective of the present invention to be comprised of a network of biocompatible tubes that are either attached to, integral with, or in close proximity to a meniscus implant. The implant is also comprised of a biocompatible material and can have interconnected porosity. The tube can have a stopping brim to prevent it from being inserted completely through the tissue. The meniscus implant / tube(s) device is located adjacent to avascular (white

or red/white) meniscal tissue such that the tubes protrude into the meniscal tissue to or through the vascular tissue (meniscus or synovium). The tube(s) provides a channel from the vascular zone of the tissue (meniscus or synovium) to the avascular or partially vascular region into or onto the meniscus implant. This meniscus implant / tube(s) device (i.e. tubes integrated or attached to a scaffold) provides a pathway through which blood, nutrients, and cells can pass to the meniscus implant so that healing and regeneration of an avascular (or partially vascular) defect or tear can be accomplished. The tube portion of the meniscus / tube(s) device can have any or all of the same features as described in the tube device alone.

[0015] It is also an objective of the present invention to provide a method for repairing damaged or diseased fibrocartilage tissue (i.e. meniscus of the knee, labrum of the shoulder, acetabular labrum of the hip, articular disc of the wrist, spinal disc, temporomandibular disc, etc.). After locating the tear or degeneration in the avascular or partially vascular zone, one of two tasks can be performed. The tissue can be removed from the inner portion of the tear (i.e. perform a partial meniscectomy) or the tear can be repaired using a number of standard repair techniques (vertical or horizontal mattress suturing, Mitek's RapidLoc™ Meniscal Repair Device for the meniscus, Bionx Arrow™ for the meniscus, etc.). If a partial meniscectomy is to be performed followed by implantation of a meniscus regenerating or replacing device or implant, then the stent can be placed into the remnant native meniscal tissue such that it provides an open channel through which blood, nutrients, and cells can flow from the vascular region of the tissue to the implant, thus facilitating healing or regeneration. After a partial meniscectomy, a meniscus / tube(s) device (i.e. tubes integrated or attached to a scaffold) could be implanted and fixed to the remaining native meniscal tissue such that the tube portion of the device protrudes into and/or through the vascular zone of the meniscus and/or synovium. The delivery of the meniscus/tube(s) device could be accomplished arthroscopically with standard techniques. The fixation could be accomplished arthroscopically as well using standard devices and techniques (suture, meniscal repair devices such as DePuy Mitek's RapidLoc, Linvatec's Bionx Arrow, etc.). If the tear is to be repaired (instead of removing the tissue via a partial meniscectomy), then the stent can be arthroscopically placed either using an all inside or inside-out technique from the outer tear surface to or through the vascular region (providing a channel)

or through both tear surfaces to the vascular region (providing a channel and a fixation for the tear), thus, facilitating repair of the avascular or partially vascular tear. Alternatively, the stent could be arthroscopically delivered using an outside-in technique.

[0016] It is also an objective of the present invention to provide a method for delivering biological treatments [i.e. blood, platelet rich plasma, bone marrow, stem cells, fibroblast cells, synovocyte cells, other cells, angiogenic factors (new blood vessel formation growth factors such as VEGF, IGF, etc...), other growth factors, hyaluronic acid, gene therapies, other biologic molecules etc.], drugs [analgesic, anti-clotting, clotting, anti-inflammatory, anti-infectives, etc...], and other substances to the tear or defect area through the tube. After the tube device is positioned or during/before the insertion process, a substance could be delivered through the tube either to the tear/defect area or to the vascular area. The substance could enhance or initiate healing, increase blood flow, improve angiogenesis, induce clotting in the duct and tear/defect, deliver cells, deliver growth factors, deliver biologic elements, etc.

[0017] It is also an objective of the present invention to provide devices as mentioned above that would be used in other joints of the body such as the hip, the wrist, the shoulder, the ankle, fingers, the toes, the spine, the temporomandibular joint, etc.

[0018] It is also an objective of the present invention to provide devices as mentioned above that would be used in cardiac muscle. For instance, if the cardiac arteries are diseased and/or blocked to the point where the cardiac muscle is starved for blood and nutrients, a tube(s) could be implanted into the cardiac muscle such that blood is delivered to the compromised cardiac muscle from an area where vascularity is more abundant.

[0019] It is also an objective of the present invention to be comprised of channel for blood, blood components, and cells to travel from a vascular area of bone to an avascular or partially vascular area, such as articular cartilage, to facilitate healing and/or regeneration in these areas that would otherwise have a lower healing and regeneration capacity. For instance, when a surgeon encounters a patient with osteochondritis dessicans (OCD), the typical surgical treatment is to remove the cartilage defect or flap and then proceed to microfracture or microdrill the subchondral bone to induce bleeding and provide a pathway for bone marrow components to aid in the healing of the OCD lesion. The surgeon, in addition to or instead of microfracturing and

microdrilling, could insert one or more stents that would retain the channel into the bone such that blood and marrow components and cells could have access to the OCD lesion, thus, improving the healing capacity of that tissue site. Also, in a spinal application, when a patient presents to a surgeon with a bulging or herniated or ruptured spinal disc, often the adjacent vertebral bone is sclerotic (i.e. thickened or more dense) and can impede the nutrient flow from the vertebral bone to the spinal disc. Therefore, the surgeon could insert one or more stents into the vertebral bone such that an open channel is created from the vertebral bone to the disc space. Alternatively, the surgeon could insert the stents into the periphery of the disc, through the outer capsule such that the capsular vascularity would have access to the spinal disc interior. This latter procedure could be performed using techniques similar to an epidural procedure.

BRIEF DESCRIPTION OF DRAWINGS

[0020] The above mentioned and other features and objects of this invention, and the manner of attaining them, will become more apparent and the invention itself will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

[0021] FIG. 1 shows a normal meniscus;

[0022] FIG. 2 shows a cross sectional view of a normal meniscus;

[0023] FIG. 3 shows a cross sectional view of a meniscus showing a vertical tear in the red/white zone;

[0024] FIG. 4 shows a cross sectional view of a meniscus showing a vertical tear in the red/white zone with a stent inserted;

[0025] FIG. 5 shows a cross sectional view of a meniscus showing a vertical tear in the red/white zone with a stent inserted and the tear repaired;

[0026] FIG. 6 shows a cross sectional view of a meniscus showing a vertical tear in the red/white zone with an inserted stent acting as a fixation device;

[0027] FIG. 7 shows a meniscus with a vertical tear;

[0028] FIG. 8 shows a meniscus with the tissue that is on the inner side of the avascular or partially vascular tear removed, i.e., with a partial meniscectomy;

- [0029] FIG. 9 shows a cross sectional view along line 9-9 of the meniscus of FIG. 8;
- [0030] FIG. 10 shows the meniscus of FIG. 9 with a stent placed therein;
- [0031] FIG. 11 shows the meniscus of FIG. 9 with a stent with a stopping brim placed therein;
- [0032] FIG. 12 shows a cross sectional view along line 9-9 of the meniscus of FIG. 8 with a stent and an implant or regeneration device;
- [0033] FIG. 13A shows a perspective view of a stent in the shape of a cylindrical tube;
- [0034] FIG. 13B shows a perspective view of a stent in the shape of a cylindrical porous rod;
- [0035] FIG. 14 shows a perspective view of a stent in the shape of a cylindrical tube with a stopping brim;
- [0036] FIG. 15 shows a perspective view of a stent in the shape of a cylindrical tube with external circumferential ribs;
- [0037] FIG. 16A shows a perspective view of a stent in the shape of a cylindrical tube with external threads 37;
- [0038] FIG. 16B shows a perspective view of a stent in the shape of a cylindrical tube with external threads having a variable pitch;
- [0039] FIG. 17 shows an elevational view of another embodiment of a stent in the shape of a cylindrical tube with external circumferential fins;
- [0040] FIG. 18 shows a perspective view of a stent in the shape of a cylindrical tube with external longitudinal ribs;
- [0041] FIG. 19 shows an end view of the stent of FIG. 16A;
- [0042] FIG. 20A shows a perspective view of a driver that is used to deliver a stent into tissue;
- [0043] FIG. 20B. shows a perspective view of a driver with the stent of FIG. 13A loaded onto it;
- [0044] FIG. 21 shows a perspective view of a driver with the stent of FIG. 17 loaded onto it;
- [0045] FIG. 22 shows a perspective view of a driver with a stent being delivered into tissue;
- [0046] FIG. 23 shows a perspective view of a driver with a delivery needle after delivering a stent into tissue;
- [0047] FIG. 24 shows a view of the stent of FIG. 16A having a lead in chamfer;

- [0048] FIG. 25 shows a perspective view of the stent of FIG. 24 having a driver slot in the back end of the stent;
- [0049] FIG. 26 shows a perspective view of a driver with raised bosses;
- [0050] FIG. 27 shows a perspective view of the slotted stent of FIG. 25 and the slot driver of FIG. 26 in the loaded condition, ready for insertion into tissue;
- [0051] FIG. 28 shows a perspective view of a knee cross section showing some of the major structures; and
- [0052] FIG. 29 shows a perspective view of a driver having a cannula.
- [0053] Corresponding reference characters indicate corresponding parts throughout the several views. Although the exemplification set out herein illustrates embodiments of the invention, in several forms, the embodiments disclosed below are not intended to be exhaustive or to be construed as limiting the scope of the invention to the precise forms disclosed.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

- [0054] FIG. 1 shows a view of a normal meniscus. The meniscus has a triangular cross section as shown in FIG 2. The top of the articulating surface 1 interfaces with the femoral condyle and the bottom of the articulating surface 4 interfaces with the tibial plateau. The inner edge 8 and the outer rim 2 are indicated in the figure. The outer wall 3 defines the outermost boundary of the meniscus tissue.
- [0055] FIG. 2 shows a cross sectional view of a normal meniscus showing approximate locations of the vascular (red) zone 7, avascular (white) zone 5, and partially vascular (red/white) zone 6 in an adult human.
- [0056] FIG. 3 shows a cross sectional view of a meniscus with a vertical tear 11 in the red/white zone 6. The inner and outer tear faces, 9 and 10, are indicated in this figure.
- [0057] FIG. 4 shows a cross sectional view of a meniscus with a vertical tear 11 in the red/white zone 6 with a stent 12 inserted at the outer tear face 10 through the vascular (red) zone 7. The tear 11 has not yet been repaired in this figure. The outer opening 13 of the stent 12 in this example is located at the meniscus outer wall 3; therefore, the stent outer opening 13 would

be positioned at the interface of the meniscus and synovium (or capsule) of the knee (See FIG. 28: items 47 & 52).

[0058] FIG. 5 shows a cross sectional view of a meniscus which has a vertical tear 11 in the red/white zone 6 with a stent 12 inserted at the outer tear face 10 through the vascular (red) zone 7. The tear 11 has been repaired using a vertical mattress suture 14 technique.

[0059] FIG. 6 shows a cross sectional view of a meniscus with a vertical tear 11 in the red/white zone 6 with a stent 12 inserted through both tear surfaces (9 & 10) from the avascular (white) zone 5 through the vascular (red) zone 7. In this example, the stent 12 acts as a tube to provide a pathway for blood, nutrients, cells, etc... from the vascular area 7 to the partially vascular area and also acts as a fixation device to approximate the inner 9 and outer 10 tear faces together. Therefore, in this example, the blood, nutrients, cells, etc... facilitate the biological healing. The fixation device also mechanically holds the inner 9 and outer 10 tear surfaces together so that healing can occur.

[0060] FIG. 7 shows a view of a meniscus with a vertical tear 11 in the avascular (white) 5 or partially vascular (red/white) zone 6 of the meniscus. The inner edge 8 and outer rim 2 of the meniscus are indicated in this figure for orientation purposes.

[0061] FIG. 8 shows a view of a meniscus with the tissue, which is located on the inner side of the avascular or partially vascular tear, removed (i.e. partial meniscectomy performed). The posterior 15, anterior 17 and outer 16 walls define the defect 18 created by the partial meniscectomy procedure. This figure represents the standard of care given by an orthopaedic surgeon to a patient with a tear or defective tissue in the avascular 5 or partially vascular 6 zone of the knee meniscus.

[0062] FIG. 9 shows a cross sectional view of a meniscus that has the inner side of the avascular or partially vascular tear 11 removed as indicated by lines 9-9 of FIG. 8.

[0063] FIG. 10 shows a cross sectional view of the meniscus after a partial meniscectomy (similar to FIG. 9) except that a stent 12 has been inserted to reach from the avascular (white) 5 or partially vascular (red/white) 6 tear face(s) (9 & 10) to or through the vascular (red) zone 7 of the meniscus to or into the synovium of the knee. In this example, the stent 12 would act to provide a channel through which blood could flow and eventually clot, creating a naturally

derived scaffold with biological factors in which cells can travel, reside, and thrive. The channel which would also have blood clotted in it would provide a pathway through which cells from the outer region could find their way to the scaffold. This combination of blood clot, biological factors, and cells would provide the proper environment for that portion of the meniscus that was removed to be regenerated.

[0064] FIG. 11 shows a cross sectional view of the meniscus after a partial meniscectomy with a stent 12 in place (similar to FIG. 10) except the stent 12 has a stopping brim 29 to impede or prevent it from advancing outwardly.

[0065] FIG. 12 shows a cross sectional view of the meniscus that has the inner side of the avascular (white) or partially vascular (red/white) tear removed (partial meniscectomy). A stent 12 that has been inserted to reach from the avascular (white) 5 or partially vascular (red/white) 6 tear face 9 to the vascular (red) zone 7. An implant or regeneration device 20 is fixed against the face 10 of the remaining meniscus such that the stent opening interfaces with the implant or device 20.

[0066] For orientation, FIG. 28 shows a perspective view of a knee cross section showing some of the major structures. The fibula 49 and tibia 50 bones comprise the lower leg thigh bones; whereas, the femur 54 is the upper leg or thigh bone. The medial meniscus 51 and lateral meniscus 55 are indicated in cross section beneath the medial condyle 52 and lateral condyle 46, respectively, and above the tibial plateau 55. The outer wall 3 of the medial 51 and lateral 47 menisci are in contact with the medial synovium (or knee capsule) 52 and lateral synovium (or knee capsule) 47, respectively.

[0067] A variety of stents 12 utilizing the principles of the present invention are illustrated in the following drawings. The illustrated stents 12 are intended for implantation in a patient for channeling blood and/or nutrients from a vascularized area 7 of the tissue to a non- (5) or less 6 vascularized area of the tissue, thus, facilitating repair of that non- 5 or less 6 vascularized tissue of the body in the patient. The illustrated embodiments would most commonly be used in repairing meniscus tissue of the knee; however, the invention is not so limited. As used herein, the term stent refers to a device that is composed of a biocompatible (bioabsorbable or non-absorbable) material and has an open channel 28 that acts to route blood, nutrients, and/or cells

from a vascular area 7 to an area that is not as vascularized (5, 6). The open channel is not required to be a through hole or unimpeded lumen 28. The open channel could be accomplished via interconnective porosity present in a biocompatible material that is configured in the shape of a stent 12 (FIG. 13B). The stent 12 acts to maintain the hole (or a channel or separation of tissue) in the tissue for a time so that blood or nutrients can be supplied to a limited vascular area to facilitate healing.

[0068] As used herein, bioresorbable, resorbable, bioabsorbable, and absorbable are intended to be interchangeable. All four terms are intended to mean materials that are naturally degradable *in vivo* over time. All are intended to include both natural and man-made materials and to include new materials, as they are developed, unless a specific material or a type of material are identified.

[0069] Referring now to FIG. 13A, the stent 12 is shown composed of a tube with an outer surface 25, an inner surface 26, and a through lumen 28. The stent 12 is ideally 2 cm or less in length but could be longer, depending on the distance between the tear or defect 11 and the vascular area 7 from which the blood, nutrients, and cells will come. The inner diameter or dimension of the lumen 28 is ideally in the 0.5 to 3.0 mm range and can be either larger or smaller depending on the actual tissue in which it is implanted. The wall thickness of the stent is ideally in the 0.1 – 1.0 mm but could be thicker or thinner as required due to the loads induced by the surrounding tissue and biomechanics. Additionally holes 27 through the outer surface 25 and inner surface 26 can be provided. The purpose of the holes 27 is to provide access ports through which blood and nutrients can flow from a vascularized area 7, as shown in FIGS. 2-6, into the stent 12. These holes 27 could be in the form of porosity or discrete holes. Ideally the hole 27 diameter will be in the 0.05 to 1.0mm range but could be larger or smaller depending on the tissue type, desired cell types, nutrients, etc... that one wishes to enter and/or exit through holes 27. Note that holes 27 do not necessarily have to be round or square or elliptical or any consistent geometry in particular but rather could be in the form of various pores of various shapes and geometries. In the case of porosity, the ideal size is in the 10 to 5000 micron range and this porosity could be either through porosity or interconnective porosity. The exit/entrance ends 13 of through lumen 28 also provides an access port through which blood, nutrients, and

cells can travel to areas of less vasculature 6 or no vasculature 5, as shown in FIGS. 2-6. These access ports 27 and 28 also provide entrance and exit pathways for cells to thrive. Note that the stents 12 shown in FIGS. 13A and 14-18 could exist without a through lumen 28. Instead, the stent 12 could be a solid appearing cylinder with porosity throughout the structure as shown in FIG. 13B. The porosity could be in the form of discrete holes that are interconnected or in the form of interconnective porosity. This same structure could be accomplished by inserting a porous cylinder into the through lumen 28 of the stent 12 shown in FIGS. 13A and 14-18 either before or after insertion of the stent 12 into tissue. Note that the outer surface 25 of the stent 12 can be smooth or can be roughened to aid in fixation of stent 12, and to increase surface area contact of stent 12 with native tissue. The roughened outer surface 25 can also act as a rasp during insertion to increase the amount of bleeding and, thus, expose more vasculature in the vascular area 7 and/or the partially vascular area 6 of the tissue.

[0070] The stent 12 illustrated in FIG. 13B is similar to stent 12 of FIG. 13A but is a porous rod. The porosity 47 can be accomplished through mechanical means (i.e. drilling, stabbing, picking, etc..) or through material means (i.e. interconnective porous material, lyophilization of slurry material, etc...) or through other means (i.e. 3-D printing, etc...). The ideal size of the pores is in the 10 to 5000 micron range. The porosity allows for blood, nutrients, and cells to travel through the stent 12 from an area of vascularity to an area of limited or no vascularity, thus, facilitating healing of the limited or no vascular tissue.

[0071] The stent 12 illustrated in FIG. 14 is similar to stent 12 of FIG. 13A but also has a stopping brim 29 so that the stent 12 can be inserted into tissue only a predetermined distance as illustrated in FIG. 11. Thus, the brim 29 would impede the stent 12 from traversing further into the tissue. The brim 29 could be circular, square, rectangular, trapezoidal, elliptical, scalloped, segmented, etc... and is required to be larger than the dimension of the outer surface 25 of the stent 12. The brim 29 as indicated in FIG. 14 is ideally 0.5 – 2.0 mm larger than the outer surface 25 dimension and is ideally 0.05 – 1.0 mm thick. This impedance function could be accomplished by a gradual transition from the smaller outer surface 25 dimension to the brim 29 dimension (i.e. ramping up from the outer surface 25 to the outer brim 29). In this case, the ramp

transition could happen over a length along the long axis of the stent 12 of 1 - 10 mm ideally but could occur over a shorter or longer length.

[0072] FIG. 15 shows a stent 12 with external circumferential ribs 36 which help with fixation of stent 12 in tissue. The tissue has elasticity associated with its material properties so that the tissue will somewhat conform to the outer geometry of the stent 12 after insertion; therefore, the external circumferential ribs 36 will become imbedded into the tissue, thus, impeding the stent 12 from moving once positioned. Tissue also has a material property commonly referred to as viscoelasticity. The tissue, therefore, will, with time, conform to the outer geometry of the stent even more. The plurality of external circumferential ribs 36 could be one or more ribs. FIG. 15 indicates four external circumferential ribs 36. The spacing between ribs 36 is ideally 2 - 10 mm; however, it could be more or less, depending on the tissue, the application, and the other dimensions of the ribs 36. Ideally the external circumferential ribs 36 extend radially outwardly from the outer surface 25 by 0.1 - 2.0 mm; however, they could extend to a greater or lesser amount as well. The axial width of the ribs 36 ideally will be in the 0.1 - 2.0 mm range but, again, could be wider or narrower, depending on the specific application. Also, the plurality of external circumferential ribs 36 that are shown in this figure are not required to share common dimensions.

[0073] FIG. 16A shows a stent 12 with external threads 37 which help with fixation of stent 12. Unlike FIG. 15, stent 12 indicated in FIG. 16A can be turned or screwed into the tissue as opposed to pushed into the tissue as with the stent 12 of FIG. 15 with circumferential ribs 36. The thread pitch or the number of threads 37 per mm or per inch can vary, depending on tissue type, other dimensions, and application, to name a few. Either a "coarse" or "fine" thread spacing could be used effectively in the stent. Ideally the external threads 37 extend from the outer surface 25 by 0.1 - 2.0 mm; however, they could extend to a greater or lesser amount as well. The axial width of the ribs 13 ideally will be in the 0.1 - 2.0 mm range but, again, could be wider or narrower, depending on the specific application. A variable pitch could also be applied to the stent 12 as shown in FIG. 16B, especially for the application indicated in FIG. 6 where the stent 12 also acts as a fixation device to pull and retain the tear 11 faces (9, 10) together. The variable pitch thread 37 could be used to ensure that the two faces (9, 10) of the tear 11 are

pushed together after implantation of the stent 12. The variable pitch would include smaller thread spacing at one end of the stent 12 with larger thread spacing on the opposite end. This variable pitch would tend to pull the two surfaces (9, 10) of the tear 11 together.

[0074] FIG. 24 shows an isometric view of the type of stent indicated in FIG. 16A. Note that the stent 12 in FIG. 24 has an added feature of a lead in chamfer 43. This chamfer 43 provides less resistance into the tissue than a blunt end as shown in FIG. 16A or 16B; therefore, with the stent 12 of FIG. 24 insertion will be easier to initiate into tissue. FIG. 19 shows a cross section 40 of the stents 12 of FIGS. 16 and 24. The non-circular cross section 40 could be used to drive the stent device 12 into tissue with a driver that has a similar cross section.

[0075] In FIG. 19, the internal cross section of the stent 12 is shown as a square or rectangle. The internal cross section could be any non-circular geometry (i.e. square, rectangle, triangle, trapezoidal, elliptical, hexagonal, star, circular with a key slot, etc...). The matching geometry of a driver 45 would be used to torque the stent 12 into the tissue. FIG. 25 shows a slotted 41 version of a threaded stent. The slot 42 interfaces with the raised boss 44 of the driver 45 indicated in FIGS. 26 and 27.

[0076] A surgeon could insert the sharpened tip 35 of the driver 45 shown in FIG. 20A, followed by the lead in chamfer 43 of the stent 12 of FIG. 24. As the surgeon turned the driver 45, the threads 37 would interface with the tissue and screw the stent 12 into the tissue. After delivery of the stent, the driver 45 could be pulled out of the stent 12 and knee joint, thus, leaving the stent 12 behind in the tissue.

[0077] FIG. 17 shows a stent 12 with external circumferential fins 38 which help with fixation into the tissue. The difference between the fins 38 and the ribs 36 is essentially the edge geometry. Where the rib 36 configuration impedes forward and backward motion equally, the configuration of fin 38 impedes motion opposite to the insertion direction. The insertion direction is indicated by the arrow 46. In other words, the fin 38 geometry is configured such that insertion of the stent 12 into tissue requires less force than removal of the stent 12 from tissue in the opposite direction from the insertion direction. The fin geometry is configured such that the forward side of fin 38 is ramped up from the outer surface 25 and back such that as the stent 12 is inserted into the tissue, the fin 38 flexes back; however, if a force in the opposite

direction of the insertion force is applied to the stent 12, then the fin 38 "digs" into the tissue to resist that force and, thus, resist motion of the stent 12 in that direction. As explained in connection with the circumferential rib 36 embodiment of FIG. 15, the tissue has elasticity associated with its material properties so that the tissue will somewhat conform to the outer geometry of the stent 12 after insertion; therefore, the fins 38 will become imbedded into the tissue, thus, impeding the stent 12 from moving once positioned, especially in the direction opposite to the direction of insertion. The tissue also has a material property commonly referred to as viscoelasticity. The tissue, therefore, will conform to the outer geometry of the stent even more with time. The plurality of external circumferential fins 38 could be one or more fins. This figure indicates three external circumferential fins 38. The spacing between fins 38 is ideally 2 – 10 mm; however, it could be more or less, depending on the tissue, the application, and the other dimensions of the fins 38. Ideally the external circumferential fins 38 extend from the outer surface 25 by 0.1 – 2.0 mm; however, they could extend to a greater or lesser amount as well. The axial width of the fins 38 ideally will be in the 0.1 – 2.0 mm range but, again, could be wider or narrow, depending on the specific application. Also, the plurality of external circumferential fins 38 that are shown in this figure are not required to share common dimensions.

[0078] FIG. 18 shows external longitudinal ribs 39 which help with fixation of stent 12. The purpose of these longitudinal ribs 39 is to resist rotation of the stent 12 about the long axis of stent 12. Since the tissue is elastic, it will somewhat conform to the outer geometry of the stent 12 after insertion; therefore, the longitudinal ribs 39 will become imbedded into the tissue, thus, impeding the stent 12 from rotating. The tissue's viscoelasticity will cause the tissue to conform to the outer geometry of the stent even more with time. The plurality of external longitudinal ribs 39 could be one or more ribs. This figure indicates four external longitudinal ribs 39. The circumferential spacing between the ribs 39 is ideally equally spaced (in this case 90 degrees apart); however, it could be more or less, depending on the tissue, the application, and the other dimensions of the ribs 39. Ideally the external longitudinal ribs 39 extend from the outer surface 25 by 0.1 – 2.0 mm; however, they could extend to a greater or lesser amount as well. The circumferential width of the ribs 39 ideally will be in the 0.1 – 2.0 mm range but, again, could be wider or narrow, depending on the specific application. The profile of the ribs 39 does not

necessarily need to be consistent from end to end. In fact, the leading edge of the rib 39 may be ramped as shown in FIG. 18 so that insertion of the stent 12 may be made easier. Also, the plurality of external longitudinal ribs 39 that are shown in this figure are not required to share common dimensions.

[0079] FIG. 20A shows a driver 45 that could be used to insert a stent 12. A surgeon could insert the sharpened tip 35 of delivery needle 33 of driver 45, followed by the stent 12 as shown in FIG. 20B or FIG. 21. As the surgeon pushed on the driver 45, the stent 12 would travel into the tissue as shown in FIG. 22. After delivery of the stent, the driver 45 could be pulled out of the stent 12 and knee joint, thus, leaving the stent 12 behind in the tissue as shown in FIG. 23.

[0080] FIG. 21 shows a perspective view of a stent 12 that is loaded onto a delivery needle 33 placed in contact with surface 40. In this position, the stent 12 is ready to be inserted into tissue. The stent indicated in this figure is the stent 12 of FIG. 17 except that it has the additional feature of a lead in chamfer 43 to facilitate ease of insertion initiation. Any of the stents 12 in the preceding figures could be shown in this figure, especially the stents 12 found in FIGS. 13, 14, 15, & 18;

[0081] A variety of materials may be used to manufacture stent 12. For example, stents could be manufactured from biocompatible polymers, biocompatible collagenous matrices, and/or any combination thereof. Other materials such as bioactive agents, biologically derived agents, inorganic materials that are biocompatible, cells, and biological lubricants can also be included as part of these components. Note that the term biocompatible polymers is intended to include both synthetic polymers and biologically derived polymers (i.e. collagen). Some examples of biocompatible polymers include: polyesters; poly-L-lactic acid (PLLA); polyglycolic acid (PGA); polydioxinone (PDS or PDO); polycaprilactone (PCL); polyvinyl alcohol (PVA); polyethylene oxide (PEO); poly(trimethylene carbonate); polymers disclosed in U.S. Patent Nos. 6,333,029 and 6,355,699; polymers derived from tyrosine; polymers derived from chitosan; polymers derived from collagenous tissues; any other biocompatible polymer that is or is not bioabsorbable, or co-polymer, or mixture of polymers or co-polymers that are used in the construction of implants. In addition, as new biocompatible materials that may be or may not be bioabsorbable are developed, it is expected that at least some of them will be useful materials

from which at least some of these components could be made. Also, the inner surface of stent 12 as well as the inner surface of the holes 27 could be configured such that an anti-coagulant material could be coated or chemically or otherwise bonded to the surface such that coagulation of the blood is impeded so as to facilitate blood flow. Note that the above materials are identified by way of example only, and the present invention is not limited to any particular material unless expressly called for in the claims.

[0082] A variety of materials may be used to manufacture the scaffold 20 of FIG. 12. For example, scaffold 20 could be manufactured from biocompatible polymers, biocompatible collagenous matrices, and/or any combination thereof. Other materials such as bioactive agents, biologically derived agents, inorganic materials that are biocompatible, cells, and biological lubricants can also be included as part of these components. Similar to the preceding paragraph the term biocompatible polymers is intended to include both synthetic polymers and biologically derived polymers (i.e. collagen), and the material listed above also apply to scaffold 20. The configuration of the scaffold material could be such that interconnective porosity is accomplished. This could be via a variety of methods, including use of nonwoven or woven or knitted fibers, foam, sponge, etc... material configurations. Again, note that the above materials are identified by way of example only, and the present invention is not limited to any particular material unless expressly called for in the claims.

[0083] When referring to ribs (36, 39), fins 38, or threads 37, the number of such could be one or more. Also, any combination of such features could be included in a stent 12.

[0084] The stents illustrated in FIGS. 13-18 and 24-25 are intended to be surgically implanted into tissue for use in helping with the repair of avascular 5 or limited vascular 6 tissue. FIG. 2 is a schematic of a human knee meniscus tissue that contains a range of vasculature. In the outer third of the periphery 3, the vasculature is abundant (red zone – 7); whereas, the inner third of the meniscus has no vasculature (white zone – 5), and the middle third of the meniscus has limited vasculature (red/white zone – 6). When a tear or defect 11 occurs in the white 5 or red/white 6 zone as shown in FIG. 3, the probability of a successful repair occurring when standard repair techniques are employed is much lower than tears or defects 11 that occur in the red zone 7 because of the lack of blood or nutrients in the white 5 or red/white 6 zones. Therefore, a stent

12, if inserted through the outer tear surface wall 10 (FIG. 4) or through both the outer tear surface wall 10 and inner tear surface wall 9 as shown in FIG. 6 and continues through the meniscal tissue to or through the red zone 7, would provide a channel 28 through which blood, nutrients, and cells could travel to the tear surfaces 9, 10 and, thus, facilitate healing of the compromised tissue. Blood can enter into the stent 12 through the end 13 of stent 12 that is inserted in the red zone 7 and/or through the holes 27 (or porosity) in the stent 12 wall (25,26). If the stent outer surface 25 were configured and the stent 12 positioned such that it could adequately approximate the tear surfaces 9 & 10 as shown in FIG. 3 (i.e. external threads 37 either consistent or variable pitch or circumferential ribs 36 or fins 38, etc...) and secure those surfaces as illustrated in FIG. 6, the stent 12 could also function as a fixation device for the tear 11.

[0085] In addition to facilitating the healing of avascular or partially vascular meniscal tears, the stents illustrated in FIGS. 13-18 and 24-25 could also be implanted surgically to facilitate healing after a partial meniscectomy (FIG. 8) of the white 5 or red/white 6 zone is performed with or without an implant or regeneration scaffold 20 in place. After a partial meniscectomy is performed (FIG. 8), the stent 12 would be inserted through the outer defect wall 16 as illustrated in FIG. 10 and continue to or through the red zone 7 of the meniscus. After the stent 12 is positioned, the meniscal implant or regeneration device 20 could be implanted into the defect created by the partial meniscectomy with whatever surgical technique is appropriate as shown in FIG. 12. The stent 12 will then function to maintain a channel 28 to allow blood, nutrients, and cells to travel to the meniscal implant or regeneration device 20 such that regeneration is facilitated. Note that the stent 12 could also be used, not only to provide a channel 28 to the vascular 7 portion, but as a fixation device to attach the meniscal implant or regeneration device 20 to the outer defect wall 16 of the meniscus. Note also that the stent 12 could be used without the meniscal implant or regeneration device 20. In this case, the stent would provide a pathway for blood to find its way to the defect and eventually clot such that a blood clot would be delivered *in situ* to the defect site. The clot would then become the scaffold (or meniscal implant or regeneration device 20). Alternatively or in addition to, a substance could be injected through

the stent 12 outer opening 13 that could then become the meniscal implant or regeneration device 20.

[0086] Stents 12 illustrated in FIGS. 13-18 and 24-25 could be implanted surgically using the driver 45 of FIG. 20A. The stent 12 could be sized to fit over the smaller diameter shaft 33 of the driver as indicated in FIGS. 20B, 21, 22, 27. The larger diameter shaft 34 of the driver acts as a shoulder 40 to push the stent 12 into the tissue. The sharp tip 35 of the smaller diameter shaft 33 would pierce or cut the meniscal tissue to allow the stent 12 to be inserted into the hole 13 that is created in the meniscus (FIGS. 22 and 23). Upon retraction of the driver, the stent 12 would remain in the tissue, being held in the tissue by friction between the stent 12 and the tissue. This frictional resistance force could be increased, depending on the design of the ribs 36, fins 38, or roughness of the outer surface 25. The stent 12 would, thus, provide a channel 28 through which blood, nutrients, and cells could travel and reside. The driver (FIG. 20A) could have an axial actuation feature between the smaller diameter shaft 33 and the large diameter shaft 34 such that after the stent device 12 is inserted in the tissue, the smaller diameter shaft 33 is retracted while maintaining the position of the larger diameter shaft 34 against the stent device 12, thus, effectively preventing the stent device 12 from retracting during the removal of the smaller diameter shaft 33. Note that the driver of FIGS. 20A & 21, could also be cannulated (i.e. have a through hole 48 along its long axis as shown in FIG. 29) such that it can be inserted over a needle (i.e. guide needle). The guide needle could be inserted first using an "all inside" or "inside-out" arthroscopic surgical technique for instance, with Linvatec's (a Conmed co.) Zone Specific® cannulae or Sharpshooter® tissue repair system. These systems allow for delivery of flexible needles to specific areas of the meniscus or knee. After the guide needle is in position, the driver (with cannulation) and stent 12 of FIG. 21 could be fed over the guide needle and into the tissue until it is in position using an "all inside" or "outside-in" arthroscopic surgical technique. Also note that the above "all inside" or "outside-in" arthroscopic surgical technique for delivery of the stent 12 could be accomplished without the use of a guide needle. Note these arthroscopic surgical techniques are commonly used by orthopaedic surgeons throughout the world.

[0087] In addition to the aforementioned push in delivery technique that has just been described above, the threaded 36 stent 12 of FIGS. 16A or 16B could be delivered with driver 45 with a delivery needle 33 that matches the non-circular cross section 40 of the internal dimension of the stent 12. Using the identical "all inside" or "inside-out" arthroscopic surgical technique described above to delivery a guide needle and the "all inside" or "outside-in" arthroscopic surgical technique described above to deliver the stent 12. The only difference is that the threaded 36 stent 12 would be turned or screwed into position as opposed to pushed into position. Therefore, the threaded 36 stent 12 position could be more easily adjusted after initial fixation has occurred.

[0088] In addition to being used in the knee for blood, nutrient, and cells to travel to defects that occur in the avascular 7 or partially vascular 6 areas of the meniscus such that repair or regeneration can occur, the stent 12 described and illustrated in the figures could also be used in many other tissues throughout the body that have similar vascular/avascular anatomies. For instance, it could be used in the labrum of the hip joint, the labrum of the shoulder joint, the meniscal-like structure of the wrist, the discs of the spine, the disc of the temporomandibular joint, diseased cardiac muscle (i.e. due to reduced blood flow from cardiovascular blockage) to name a few.

[0089] It not only could be used in "soft tissue" such as meniscus, discs, labrum, cartilage, etc..., but it could also be used in bone. For instance, in spinal applications when a patient presents to a surgeon with a bulging or herniated or ruptured spinal disc, the adjacent vertebral bone is often sclerotic (i.e. thickened or denser). Since much of the nutrients for the spinal disc are delivered via diffusion through the vertebral endplates, the sclerotic bone could tend to decrease the amount of nutrients delivered to the disc, thus contributing to the diseased state of the disc; therefore, if one or more stents 12 were placed through the sclerotic bone of the adjacent vertebra, then blood, nutrients, and cells could be delivered to the damaged or diseased disc and, thus, facilitate repair of the tissue. Also, for cartilage or cartilage/bone defects caused by the disease called osteochondritis dessicans (OCD), the typical surgical treatment is to remove the cartilage defect and then proceed to microfracture or microdrill the subchondral bone (i.e. the bone beneath the articular cartilage defect) to induce bleeding and provide a pathway for bone

marrow components to aid in the healing of the OCD lesion. Therefore, the surgeon, in addition to or instead of microfracturing and microdrilling, could insert one or more stents 12 into the subchondral bone so that a channel would be retained in the bone such that blood, marrow components, nutrients, and cells could have access to the OCD lesion, thus, improving the healing capacity of that tissue site. Also, the stent 12 could be used in bone applications where non-union fractures occur. For instance, it could be inserted into the bone on either side of the fracture point(s) such that a fresh hematoma (mass of blood) may be created at or near the fracture site and thus facilitate repair or union of the fracture.

[0090] While most of the descriptions here have referred to a single stent 12 in these applications, it is likely that multiple stents 12 will be used to facilitate the repair of tissue. The spacing between stents 12 will depend on the tissue to be healed, the extent of damage, the type of defect, the native tissue, etc...; however, for a typical vertical tear that may occur in the knee meniscus avascular 7 or partially vascular 6 area, the spacing will likely be in the 5 – 10 mm range with larger or smaller spacing potentially.

[0091] After the stent 12 is implanted in tissue, it could also function as a portal through which biological treatments [i.e. blood, platelet rich plasma, bone marrow, stem cells, fibroblast cells, synovocyte cells, other cells, angiogenic factors (new blood vessel formation growth factors such as VEGF, IGF, etc...), other growth factors, hyaluronic acid, gene therapies, other biologic molecules etc.], drugs [analgesic, anti-clotting, clotting, anti-inflammatory, anti-infectives, etc...], and other substances could be delivered to area of interest. The treatment could enhance or initiate healing, increase blood flow, improve angiogenesis, induce or prevent clotting in the duct and tear/defect, deliver cells, deliver growth factors, deliver biologic elements, etc.

[0092] While this invention has been described as having a preferred design, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

WHAT IS CLAIMED IS:

1. A surgical stent for avascular or partially vascular tissue repair and regeneration, said stent comprising an elongated member made of a biocompatible material, said member having a passage therein, said member having an outer surface, whereby said stent may be implanted in a patient to deliver blood, nutrients, and cells from an area of vascular tissue through said passage to an area of tissue with little or no vasculature.
2. The stent according to claim 1 wherein said member comprises a hollow tube which is open at both ends to define end apertures.
3. The stent according to claim 2 wherein the wall of the hollow tube includes a plurality of apertures to enable blood, nutrients, and cells to enter the stent from vascular tissue.
4. The stent according to claim 2 wherein the outer surface of the tube is smooth.
5. The stent according to claim 2 wherein the outer surface of the tube is roughened.
6. The stent according to claim 2 wherein the outer surface of the tube includes ribs.
7. The stent according to claim 6 wherein the ribs encircle the outer surface.
8. The stent according to claim 6 wherein the ribs comprise threads to enable the stent to be threaded into tissue.
9. The stent according to claim 8 wherein the threads have varying pitch across the length of the threads.
10. The stent according to claim 6 wherein the ribs include sharp outer edges.
11. The stent according to claim 6 wherein the ribs are longitudinal and parallel to the longitudinal axis of the tube.

12. The stent according to claim 2 wherein one of said end apertures comprises at least one of a non-circular aperture to enable a driving tool to engage said aperture to rotationally drive said stent into tissue.

13. The stent according to claim 11 wherein one of said end apertures comprises a slot.

14. The stent according to claim 2 wherein said stent includes a collar for limiting the travel of the stent into tissue.

15. The stent according to claim 1 wherein said member comprises a porous rod.

16. A surgical stent for avascular or partially vascular tissue repair and regeneration, said stent comprising a rod made of a biocompatible material, said rod having one of a plurality of interconnected apertures and porosity to define a passage, said rod having an outer surface, whereby said stent may be implanted in a patient to deliver blood, nutrients, and cells from an area of vascular tissue through said passage to an area of tissue with little or no vasculature.

17. The stent according to claim 14 wherein the outer surface of the rod is smooth.

18. The stent according to claim 14 wherein the outer surface of the rod is roughened.

19. The stent according to claim 14 wherein the outer surface of the rod includes ribs.

20. The stent according to claim 17 wherein the ribs encircle the outer surface.

21. The stent according to claim 17 wherein the ribs comprise threads to enable the stent to be threaded into tissue.

22. The stent according to claim 17 wherein the ribs include sharp outer edges.

23. The stent according to claim 17 wherein the ribs are longitudinal and parallel to the longitudinal axis of the tube.

24. The stent according to claim 14 wherein at least one end of said rod has a non-circular geometry to enable a driving tool to engage said aperture to rotationally drive said stent into tissue.

25. The stent according to claim 14 wherein the rod includes a collar for limiting the travel of the stent into tissue.

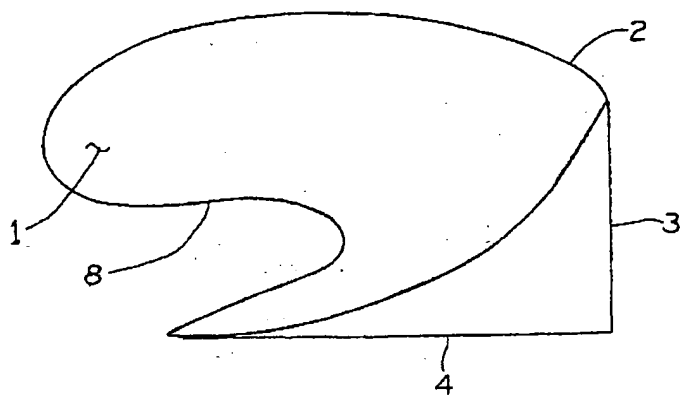


FIG. 1

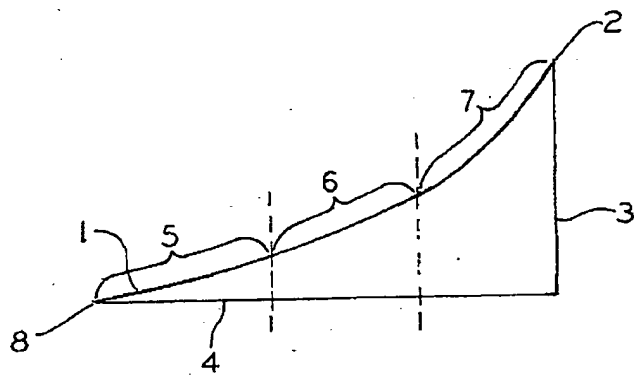


FIG. 2

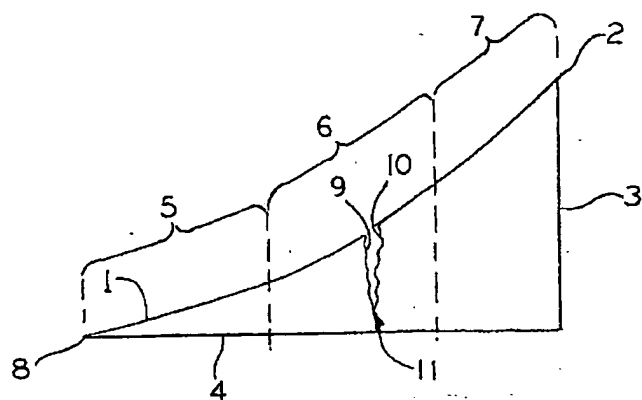


FIG. 3

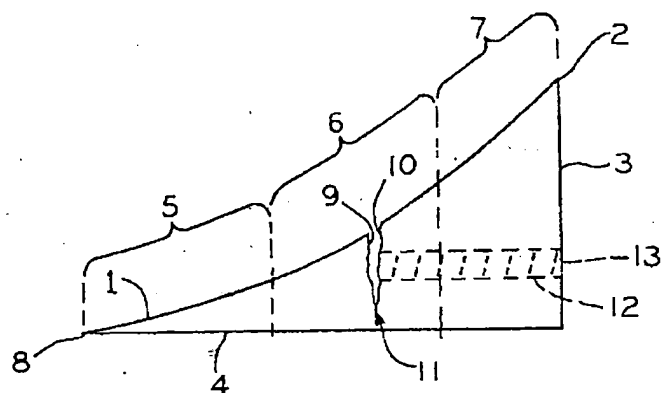


FIG. 4

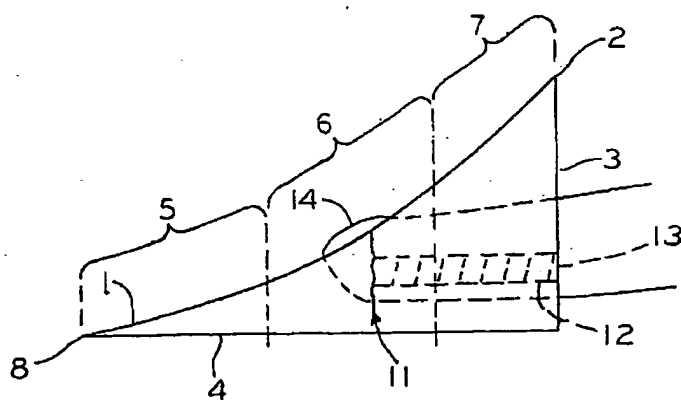


FIG. 5

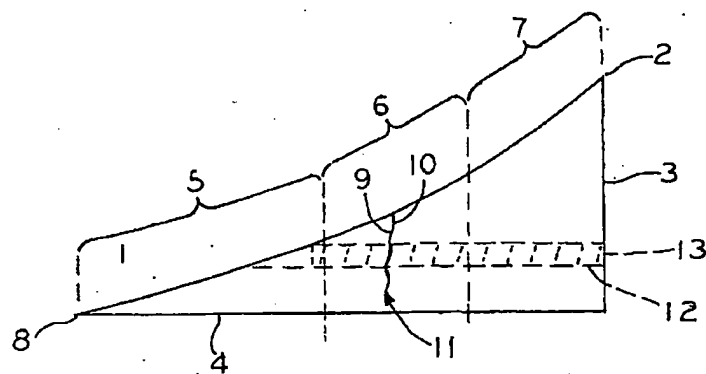


FIG. 6

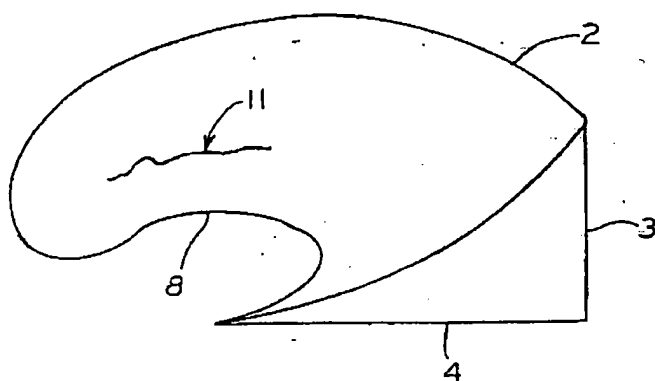


FIG. 7

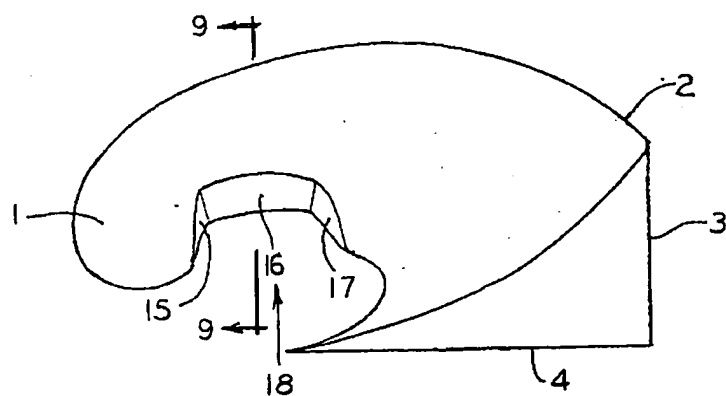


FIG. 8

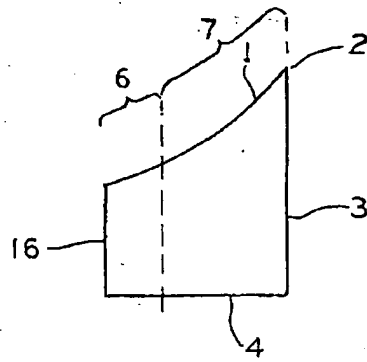


FIG. 9

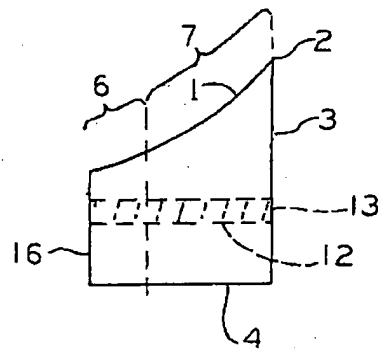


FIG. 10

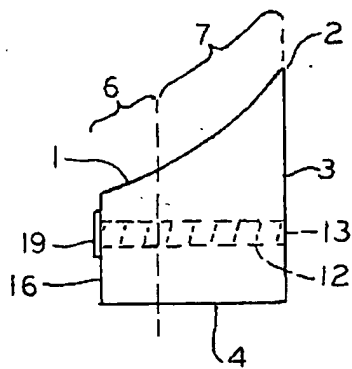


FIG. 11

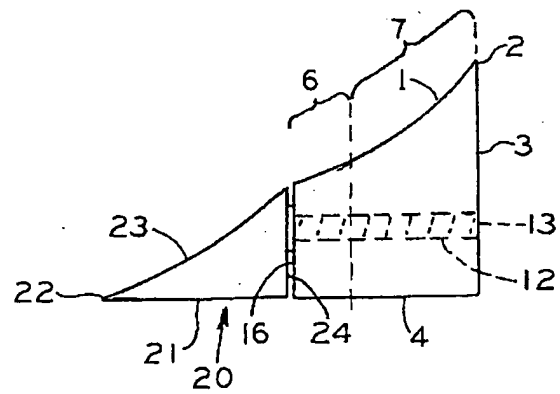


FIG. 12

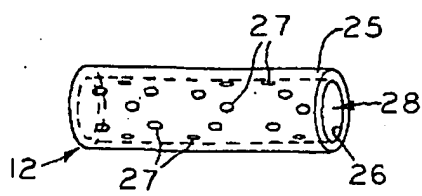


FIG. 13A

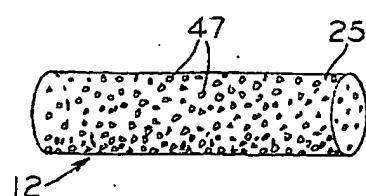


FIG. 13B

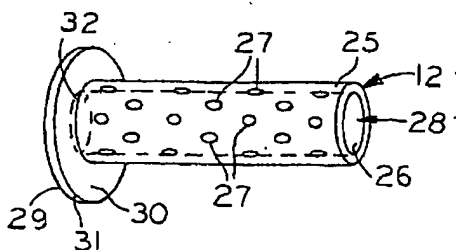


FIG. 14

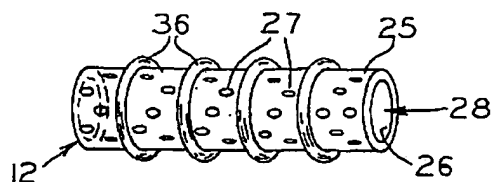


FIG. 15

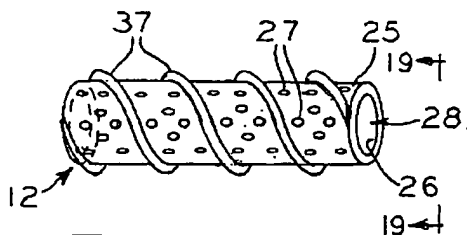


FIG. 16A

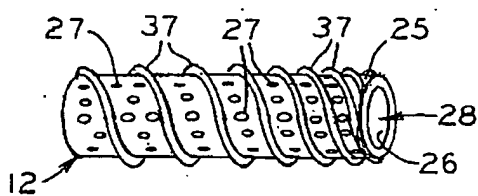


FIG. 16B

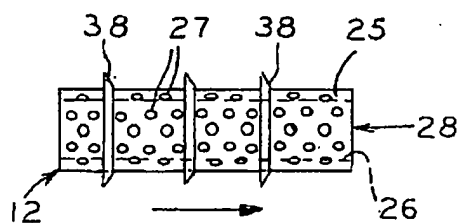


FIG. 17

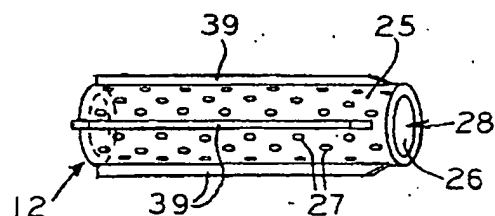


FIG. 18

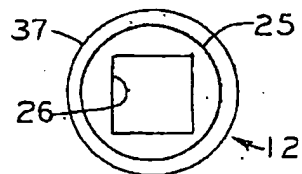
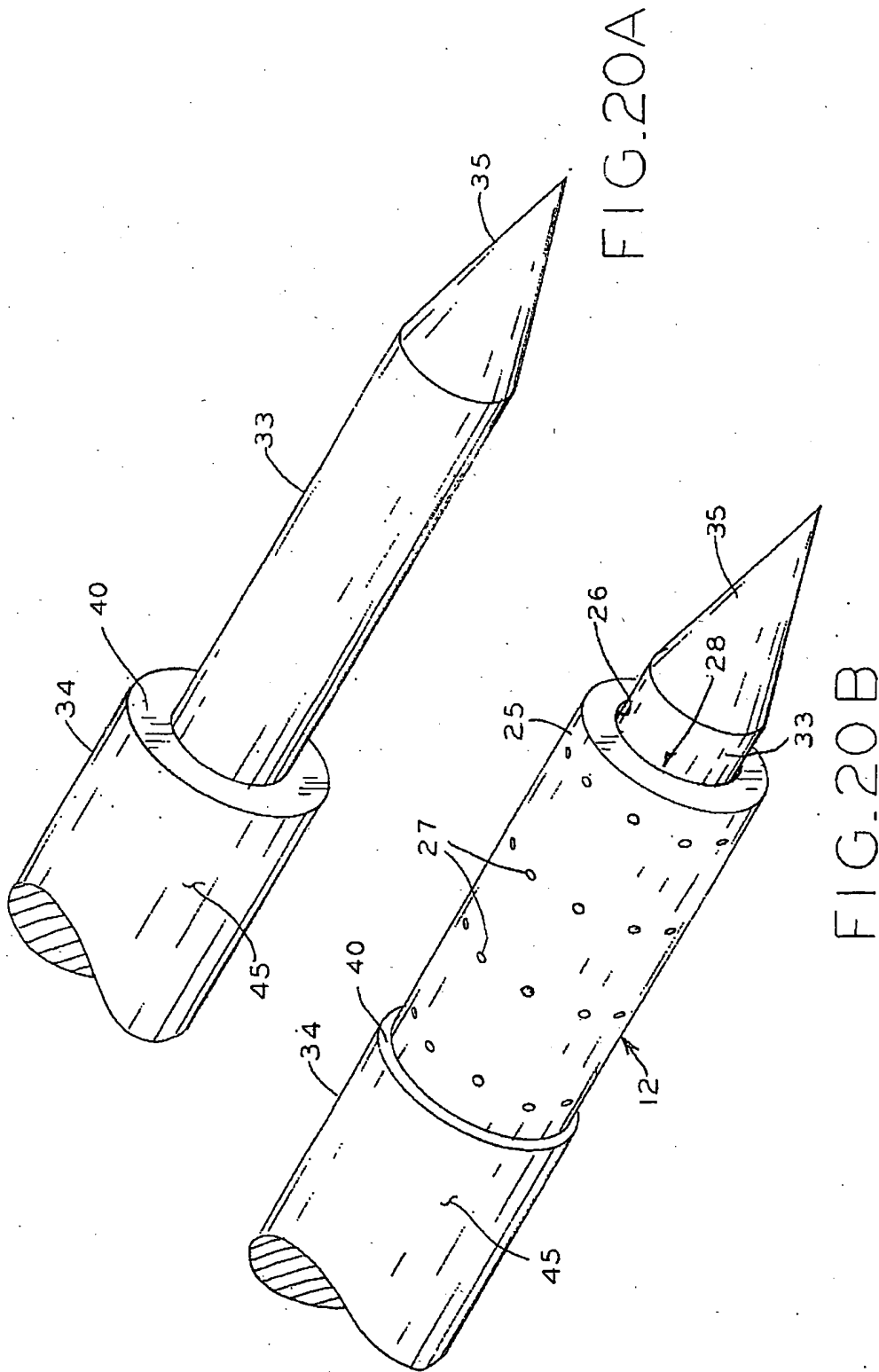
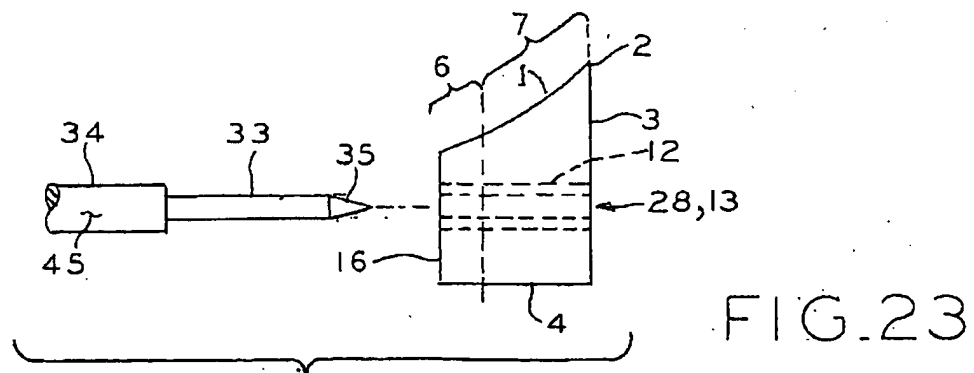
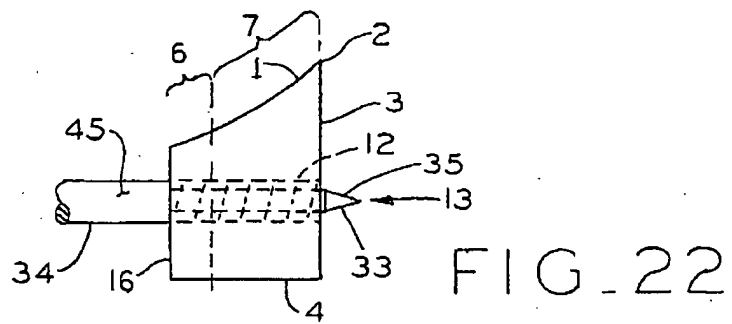
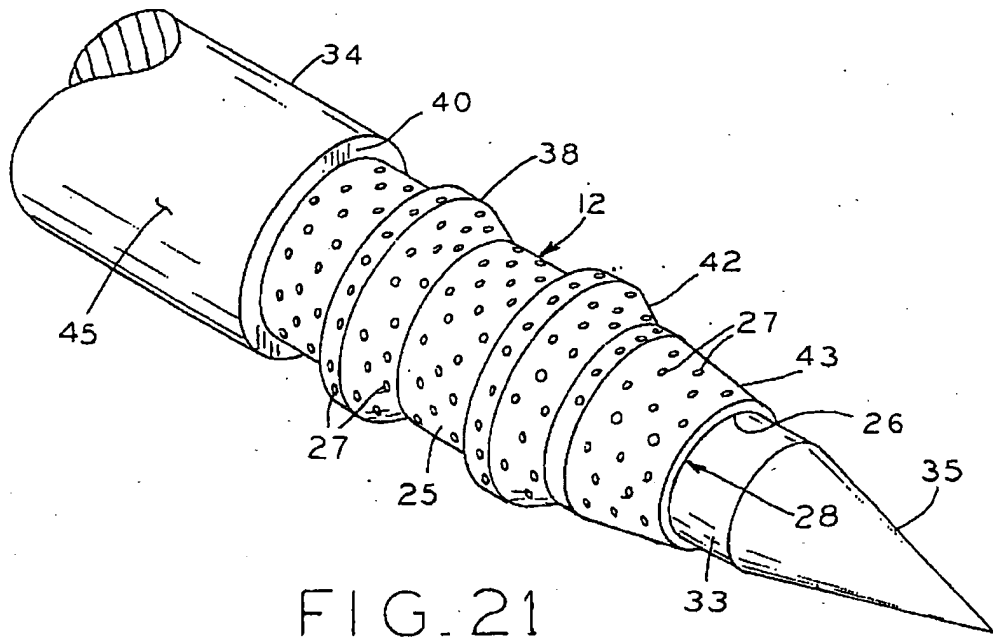


FIG. 19





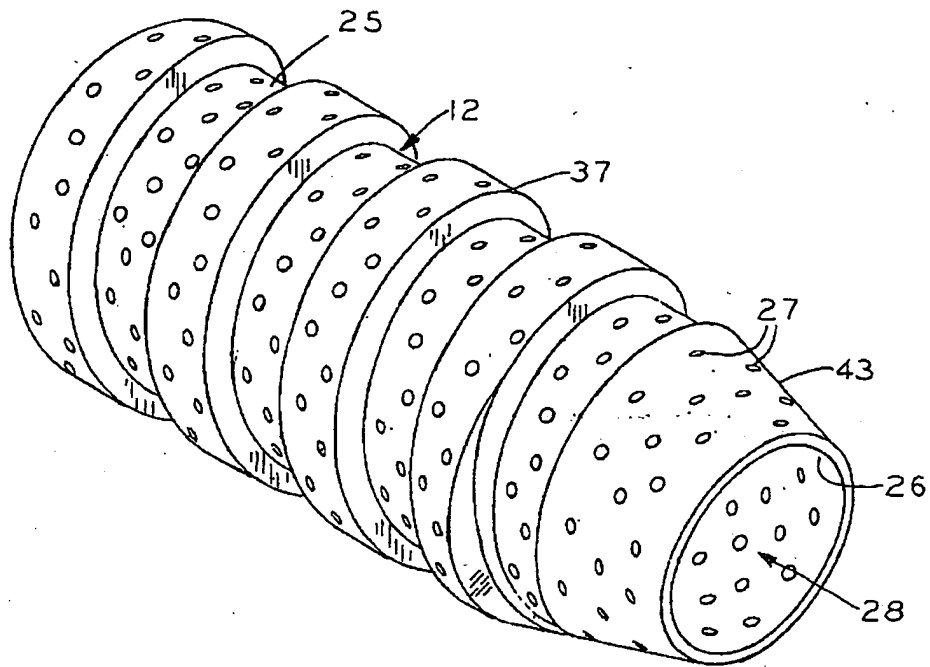


FIG. 24

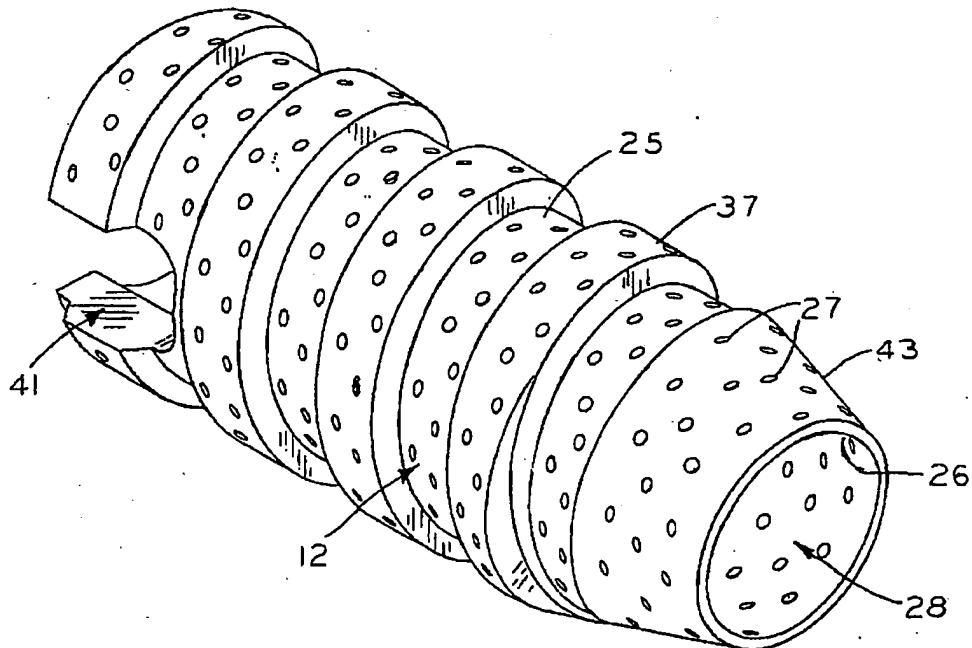


FIG. 25

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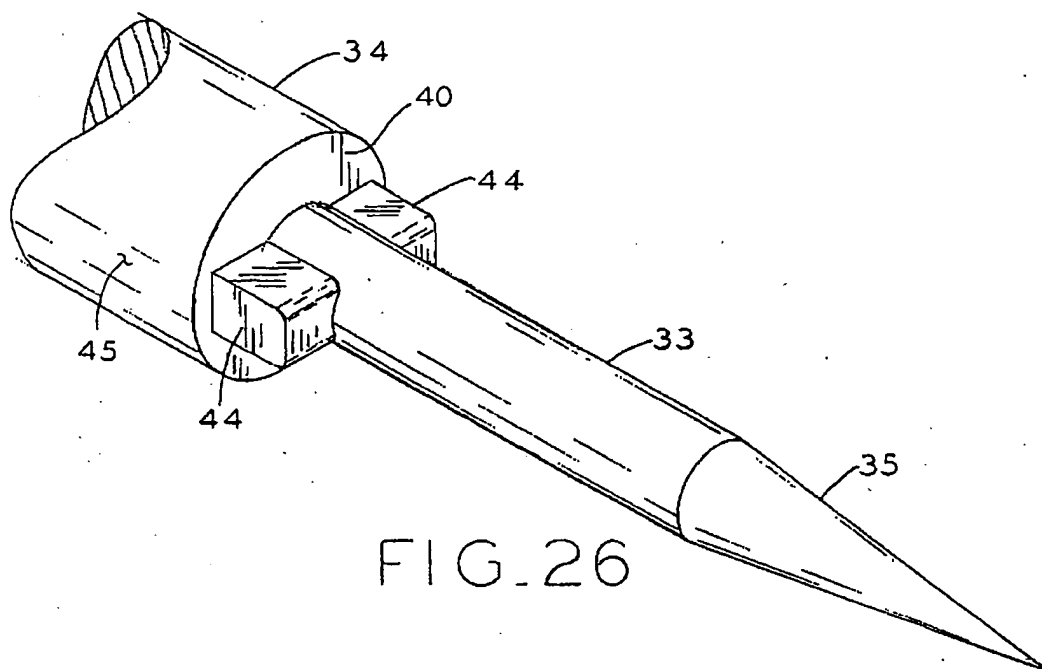


FIG. 26

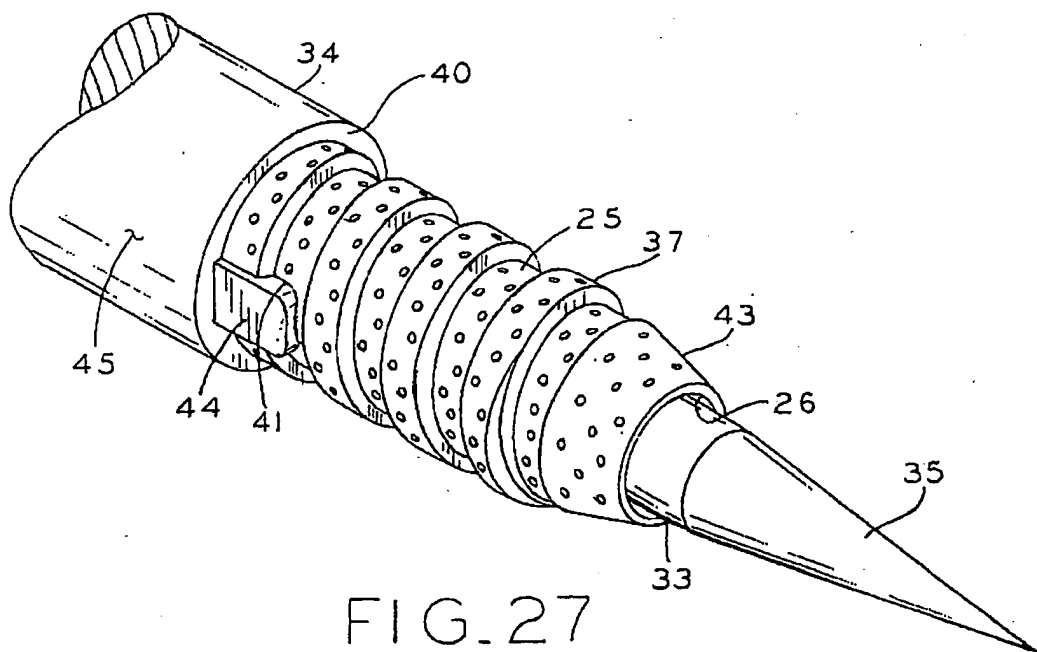


FIG. 27

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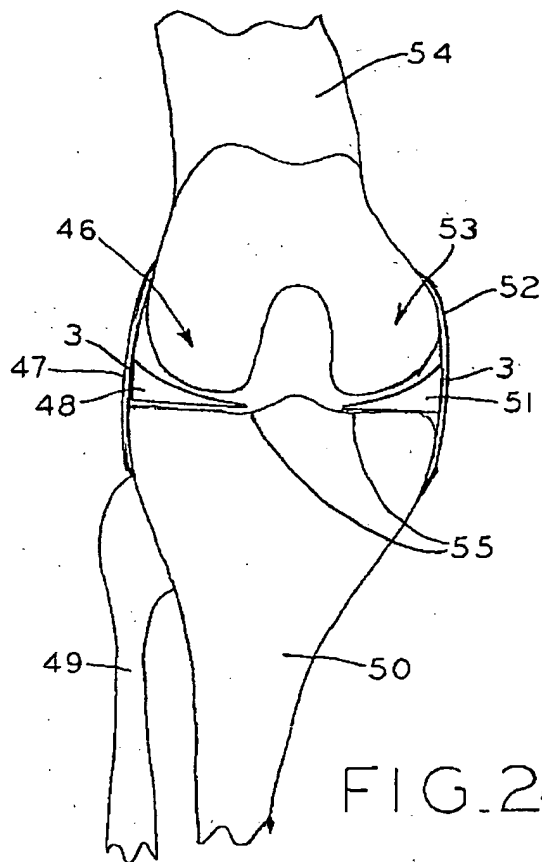


FIG. 28

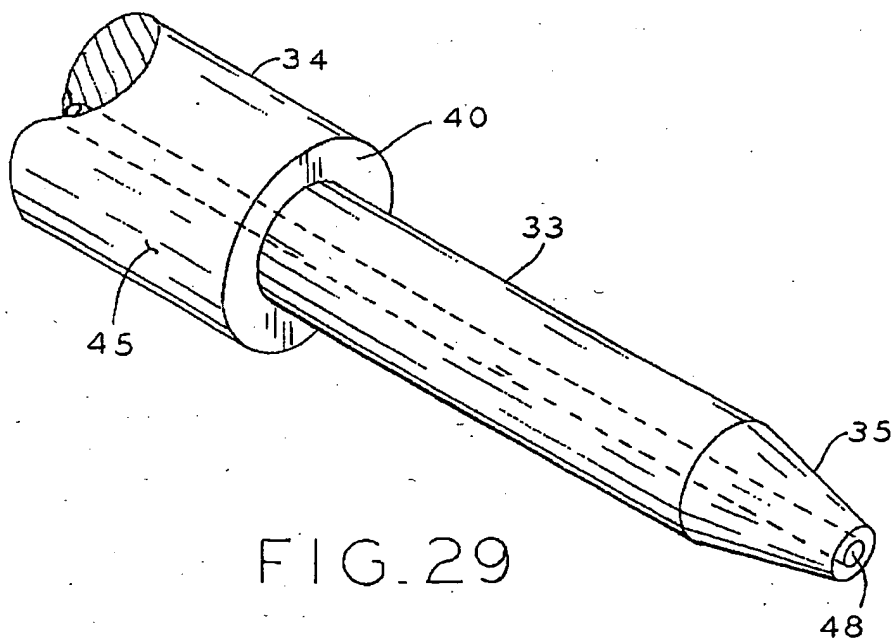


FIG. 29

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/13973

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/06

US CL : 623/1.11,1.15; 606/198

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1.11,1.15; 606/198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,725,549 A (LAM) 10 March 1998, figures 1-19.	1-25

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

<p>* Special categories of cited documents:</p>		"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

21 July 2005 (21.07.2005)

Date of mailing of the international search report

31 AUG 2005

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